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STANDING COMMITTEE OF EUROPEAN DOCTORS

Organ donation and transplantation:

European Commission working documents and stakeholders meeting

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From: Eduardo.FERNANDEZ-ZINCKE@ec.europa.eu
Sent: vendredi 25 avril 2008 10:15
Subject: key stakeholder group on organ donation and transplantation

Dear members of the key stakeholder group on organ donation and transplantation:

As agreed please find enclosed the latest update of the European Commission working documents on organ donation and transplantation. **Please note that these documents do not represent the official position of the European Commission or its services.**

As you know the first document contains the elements of action intended to strengthen cooperation between Member States on organ donation and transplantation that addresses the main policy challenges and identifies 10 priority areas. The second document is a draft set of basic safety and quality principles and technical requirements to ensure common standards of safety and quality in the donation, procurement, testing, preservation, transport and distribution of human organs.

In addition, on 22 April 2008, the European Parliament's adopted a report welcoming the Commission's continued work in this field.

The next step of the process will be to focus on impacts of the future initiatives. Further consultation will be held at an open stakeholders meeting in 23 May 2008 in Brussels. All you are welcome to attend; unfortunately the Commission can not reimburse cost. The Information for the registration on that meeting is available on http://ec.europa.eu/health/ph_threats/human_substance/registration_230507.htm

I would thank you very much for your valuable support and advice in this process. Please do not hesitate in contacting us for further comments or clarifications.

Best regards

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EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Brussels, 28 April 2008
D(2007)

DRAFT WORKING PAPER

ON AN ACTION PLAN ON ORGAN DONATION AND TRANSPLANTATION[1] (2009-2015)

1. INTRODUCTION

Analysis of the organ transplantation situation in the EU Member States has revealed large differences in the deceased and living organ donor rate within the EU and also considerable differences in transplantation activity. Even though these differences cannot be easily explained, it is clear that some models are performing better than others.

On 31 May 2007 the Commission adopted a Communication on organ donation and transplantation[2]. This Communication and the Impact Assessment[3] attached to it identified the main challenges to improving organ donation and transplantation in the EU and proposed two mechanisms of action: a legal instrument containing the basic quality and safety principles in organ donation and transplantation and an action plan for a strengthened cooperation between Member States.

With this working document the Commission is seeking to set out a more detailed list of priority actions specifically tailored to the field of organ donation and transplantation. These priority actions are grouped under three key goals:

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

Some of these actions require **EU involvement and direct action**, whereas others actions could be included in **National Action Plans**. In the latter, implementation of

[1] **This document does not represent an official position of the European Commission or its services. The suggestions contained in this document do not prejudge the form and content of any future proposal by the European Commission.**

[2] SEC(2007) 704 – SEC(2007) 705

[3] Impact Assessment of 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

these actions fall mainly under Member State responsibility with the Commission providing a coordination and facilitation role.

THE RATIONALE FOR A STRENGTHENED COOPERATION ON ORGAN DONATION AND TRANSPLANTATION

Organ shortage is a common problem faced by all European countries. The excellent results of transplantations during the last decade, in terms of life years gained and improvement of quality of life, have significantly increased the demand of organs transplants and the number of patients on waiting lists. Unfortunately, the increase in organ donor rates has not been sufficient to meet the rising demand. A comprehensive description of the factors contributing to the severe scarcity of organs is available in the Impact Assessment of the Communication on organ donation and transplantation: Policy actions at EU level[1].

Sharing experience and expertise across the EU Member States has already proved useful in increasing organ donor rates in some countries and this can be further developed with a view to establishing efficient systems for identifying potential donors. Member States can join efforts and expertise in order to increase public awareness, which would as a consequence increase organ availability. Further cooperation can also be geared towards exploring the use of "expanded" donors and living donation.. Those Member States whose transplant systems are not yet sufficiently developed can be supported and guided in their efforts to improve patient care.. Facilitating the interchange of organs between Member States (especially for children, urgent or difficult to treat patients), promoting EU-wide agreements on issues concerning transplantation medicine and the collection of activity data for benchmarking purposes can further improve the efficiency and accessibility of transplantation systems. The European Commission can also promote cooperation between Member States on research programmes and training of professionals

Cooperation between Member States can improve some aspects of **quality and safety** of organ donation and transplantation, and complement the legal instrument on quality and safety. Strengthened coordination between countries can lead to the compilation of sufficient information for the evaluation of post-transplant results and the promotion of good medical practices. This data can assist in determining the acceptable levels of risk in the use of expanded donors and facilitate the exchange of best practices on living donor protection.

Art.152 of the Treaty providesthe possibility for the EC to adopt harmonising measures to ensure organ safety and quality. The same article 152 (par.2) states that Community action shall also complement national policies directed towards improving public health. In fact, the Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. In this respect Member States shall, in liaison with the Commission, coordinate their policies and programmes among themselves. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.

This cooperation approach should be based on the identification and development of common objectives, agreed quantitative and qualitative indicators and benchmarks, regular reporting, and identification and sharing of best practices.

Member States should themselves decide on the actions to include within their National Action Plans, this action plan should serve as a platform for discussion, exchange of

expertise, and identification of best practices. The National Action Plans (NAPs) should be country specific and tailored to the specific situation in every MS.

In addition to the NAPs there are actions which **the Community should undertake to contribute to the agreed objectives.**

There is a huge potential for sharing experience and expertise among EU Member States. Cooperation between countries can significantly improve quality and safety of organ donation and transplantation, increase organ availability and enhance the efficiency of the transplantation systems in the EU Member States.

2. JOINT OBJECTIVES AND PRIORITY ACTIONS FOR ORGAN DONATION AND TRANSPLANTATION

In recent years, the Commission has put considerable effort into supporting the area of organ transplantation under different Community programmes. A large number of projects have been funded[4]; the results of which have generated a considerable amount of useful information and knowledge for activating EU policies in this area. It is now time for these ideas to be put into effect.

In June 2006 the Commission launched an open consultation on organ donation and transplantation. Based on the outcome of this consultation, the Commission proposes future initiatives to be taken at Community level that have added value in addressing the challenges ahead. Furthermore, it identifies actions which can be taken by Member States at national level.

2.1. GOAL 1 Increasing organ availability

The severe shortage of organs remains the main challenge that EU Member States face with regard to organ transplantation. Nearly ten patients die everyday while waiting for an organ in Europe. Waiting lists are increasing faster than organ donor rates.

Actions aimed at increasing organ availability will not only increase the number of life-saving transplantations but also have a positive impact on the quality of life, increasing healthy life years and reducing suffering for many patients and their families. The following objectives shall be met by Member States in cooperation with the Commission:

Objective 1: Member States should advance towards their full potential of deceased donations. The Commission should monitor such development through appropriate indicators.

Priority action 1: Establishment of efficient systems for identifying those patients that could become organ donors upon their death. Promote the role of transplant donor coordinators in hospitals .

Policies should encourage hospital intensive care units to engage actively in organ donation by the detection of brain death potential donors.

[4] A description of the projects is available in the Impact assessment attached to this Communication.

The combination of an efficient system for organ donor identification, detection and procurement has been identified as a key element in increasing the deceased donation rates in those countries that have not reached their full potential.

The presence of a key donation person at hospital level, having as their main responsibility the development of a proactive donor detection programme, represents the most important step to optimizing organ donation and improving donor detection rates. He/she will be mainly responsible for integrating the development of donor detection programmes and specific protocols, defining local benchmark figures and targets for improvement.

The key figure could also be responsible for the progressive involvement in training, education, promotion and research. Considering all these responsibilities and depending on the donation and transplantation activities within a specific hospital, it could be more convenient to considering a team of persons in charge of donation than only referring to a sole figure. This team should include the sufficient number of qualified personal in order to efficiently develop the activities of donation.

The implementation of the Council of Europe Recommendation Rec (2005)11 on the role and training of professionals responsible for organ donation (transplant "donor co-ordinators") should be monitored and supported.

Priority Action 2: Establish efficient systems for identifying those patients who could become organ donors upon their death. Promote Quality Improvement Programmes in every hospital where there is a potential for organ donation

The Quality Improvement Programme is primarily a self-evaluation of the whole process of organ donation, jointly performed by the specialists in intensive care and the transplant co-ordinator of every hospital.

The Council of Europe Recommendation Rec (2006)16 of the Committee of Ministers to Member States on Quality Improvement Programmes for organ donation recommends that appropriate standards should be defined in every country according to the characteristics of the hospital and the health system in order to compare the results with those of other regions or countries, so as to better define the areas for improvement like brain detection, organ evaluation and family refusal etc. The implementation of this recommendation should be monitored and supported.

<u>Objective 2:</u> Member States should promote the implementation of programmes of living donation following best practices. The Commission should support and monitor such development through appropriate indicators.

Living donation has been growing strongly in recent years, thanks to the advances in the field of organ transplantation. The choice of transplantation from a living donor offers some advantages compared to that from a deceased donor. However, it also carries disadvantages related to donor risks in terms of health and safety, and there are several controversial ethical aspects to be taken into account.

Priority Action 3: Exchange of best practices on organ living donation programmes among EU Member States: Support registers of living donors.

There is no specific recommendation by the European Union on standards related to quality and safety for the living donation process, and there is a great heterogeneity among European countries legislations, ethical concerns, protection systems and donor's data registries on this topic.

Living donation is a real alternative to improving the availability of organs for transplantation. However, living donation programs should be complementary to the deceased ones and never in competition with them. Adequate tools (such as local, national or international registries, as well as periodic surveys and others) should be developed in order to ensure that information on the medical, psychological, financial and social consequences related to living donation, in the short and the long term is properly collected. This information should help to develop evidence based guidelines and consensus documents, addressing the selection, evaluation and follow-up of the living donor.

Objective 3: Increase public awareness on organ donation.

Public awareness and opinion plays a very important role in increasing organ donation. Continued education should form an essential element of any communication strategy. People should be encouraged to speak about organ donation and to communicate their wishes to their relatives. Only 41% of European citizens have discussed organ donation within the family[5]. There is an important positive correlation between having discussed it within the family and willingness to donate organs.

Priority Action 4: Improve Knowledge and communication skills of health professionals and patients support groups on organ transplantation

Health-care professionals, whether directly or indirectly involved in the process of organ donation must be aware of the importance of using clear, understandable and credible information on organ donation and transplantation which promotes a feeling of confidence in the sytem as a whole.. Health-care professionals are responsible for identifying potential donors, approaching the grieving families and/or providing general information on the process of organ donation and transplantation. In order to ensure a positive social climate on organ donation, they need special support and skills training.

Improving knowledge about transplantation issues in health care professionals, the media and the general public, seems to be one of the most cost-effective means of increasing public willingness to donate. Both positive and negative messages can have an impact on the general public's willingness to donate, thus there is a need for communications experts to become involved in organ donation campaigns. An open and transparent relationship between transplant organizations and the mass media should be ensured and cultivated. Managing adverse publicity must be combined with an adequate and systematic spread (via the media to the medical and lay community) of the positive and life-enhancing aspects of organ donation and transplantation. Also, periodic meetings of journalists, experts in communication and opinion leaders in transplantation could represent a pragmatic approach to influence and educate the media in issues related to transplantation.

[5]Eurobarometer survey 2006

Priority Action 5: Facilitate the identification of organ donors across Europe and cross border donation in Europe .

The interplay of different consent systems in the Member States creates uncertainty with respect to donor wishes when he/she dies outside their country of origin. Some Member States requires presumed consent while other Member States require an explicit consent (e.g. in a consent form or donor card) before donation can proceed. National authorities are responsible for determining the legal requirements and practices regarding donation consent, and for ensuring that their citizens are aware of their rights, but is also important that citizen are aware of how consent is organised in other Member States.

In view of the increasing cross-border mobility of European citizens, mechanisms should be developed that could facilitate the identification of organ donors across Europe and therefore increase the availability of organs for life-saving transplantations and difficult to treat patients (paediatric, hypersensitised patients).

These initiatives could further ensure that citizens are informed about their rights concerning organ donation across the EU.

2.2. GOAL 2 Enhancing the efficiency and accessibility of transplantation systems

The proposed measures aiming at enhancing the efficiency and accessibility of transplantation systems will have a positive impact on transplantation activity. Support and guidance for Member States with less developed transplant systems can lead to a huge improvement in terms of donation rates; number of organ transplantations carried out; and post-transplant results. Training of professionals, cooperation in the field of research, EU-wide agreements on aspects of transplantation medicine and the collection of transplantation activity data will have a medium to long-term positive impact on transplantation activity and the success of organ transplantations.

Objective 4: Support and guide transplant systems to be more efficient and accessible

It is important to develop common approaches with a consistent methodology in data collection to enable benchmarking and comparative analysis of organ donation in different Member States. This will lead to the development of a set of effective indicators to evaluate the performance of transplantation systems. This will permit ad hoc recommendations of the committee of experts to Member States on the basis of the regular reporting to be included in the national actions plans.

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

Organisational structures not only have an impact on quality and safety of organs but also on the detection, referral and hence the availability of organs. The organizational structure is an important key to organ donation/transplantation systems. There is a need for a well organized and effective transplant system. Such a system needs an appropriate legal framework, a good technical approach and organizational support.

Even among EU countries having well-developed services, there are still considerable differences in organ donation and transplantation activity and some organisational

models seem to be performing better than others. Initiatives will be focused on identifying the most efficient systems, sharing experience and promoting best practices in accordance with local characteristics.

Those Member States whose transplant systems are not yet sufficiently developed can be supported and guided in their efforts to improve patient care. The use of Structural Funds, Twinning Projects or network of centres of reference could be explored.

Priority Action 7: promote EU-wide agreements on aspects of transplant medicine

A cooperation method is an ideal context to discuss issues of mutual concern in order to come up with common and shared solutions and monitor their implementation through agreed mechanisms. This cooperation method seems especially pertinatn in identifying the main challenges related to increasing patient mobility, and in particular, for border regions and small member states.

The severe organ shortage significantly restricts access to transplantation services in many EU member states. As a result, urgent patients increasingly seek transplantation services in countries with bigger donor pools and shorter waiting lists. Increased coordination between EU Member States is therefore required with regard to exchange of patients, admission criteria, (multiple) waiting lists registration, and reimbursement procedures.

It is also important to secure EU-wide agreement on every issue concerning transplant medicine for extra-Community patients

It will also be desirable to promote a common understanding on the priorities and strategies for the future research programmes. The creation of a European transplant research network could be considered.

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

Procedures and IT tools for offering surplus organs to other countries can be evaluated, with special reference to the exchange of organs for urgent and difficult to treat patients.

Every year a number of organs are exchanged between EU Member States. However the number of organs interchanged between Member States constitutes a low percentage of the total of organs used for transplantation with the exception of the Eurotransplant and Scandiatransplant areas.

Urgent patients and difficult recipients (children, highly sensitised patients, etc.) may not be treated as efficiently within a small transplant organisation compared to a large one. This is of particular concern for small Member States with a smaller donor pool..

2.3. GOAL 3 Improving quality and safety

Objective 5: Improving the quality and safety of organ donation and transplantation.

Improving quality and safety of organ donation and transplantation will have an impact on risk reduction and consequently on reduction of co-mortality and co-morbidity of patients.

The Communication on organ donation and transplantation proposed an appropriate and flexible European legal framework as an adequate community response to meet the mandate provided in Art. 152.4 a). of the Treaty. The future legal instrument based on a separate impact assessment, could include the principles needed to establish a basic quality and safety framework, including for example the creation of national competent authorities and other relevant structures.

This action plan should complement the legal framework with the compilation of sufficient information in form of registers that can facilitate the evaluation of post-transplant results and contribute to the development of good medical practices in organ donation and transplantation. The data can furthermore assist in determining the acceptable levels of risk in the use of expanded donors.

Priority Action 9: Evaluation of post transplant results.

The aim of this action is to develop common definitions and methodologies to evaluate the results of transplantations. This action could facilitate the promotion of EU wide registers or the methodogy to compare the results of existing post –transplant follow up registers on organ recipients This will permit the elaboration and promotion of good medical practices on organ donation and transplantation.

In order to increase the pool of organs available for transplantation, the use of expanded donors can be considered. The critical shortage of organs, the morbidity and mortality of patients awaiting transplantation have mandated careful reconsiderations of other potential donors who were not ideal candidates.

Published experience is not enough to establish safety limits in practice. Cooperation between countries through post transplant follow up will give a higher number of recorded charts which will help to define quality and safety practices guidelines for those cases. The compilation of sufficient information will assist in determining the acceptable levels of risk in the use of expanded donors

Priority Action 10: Promote a common accreditation system for organ donation/procurement and transplantation programmes

To develop methodology that could support the EU legal framework for the accreditation of programmes of organ donation, procurement and transplantation. This could help to build a common accreditation system at EU level.

4. THE MECHANISM OF COORDINATION

The mechanism of coordination should be devised as an instrument to achieve common objectives and **share best practices** in this area which remains primarily the responsibility of national governments whilst at the same time concerns the EU as a whole.

It should be a process by which **common objectives/guidelines** are established, **best practices** are identified and compared by means of jointly-agreed quantitative and qualitative **indicators** and **benchmarking**. The measures to be taken in order to achieve the objectives are decided upon in the context of **national action plans.** A **reporting system** on regular basis facilitates the evaluation of progress made by the Member States in achieving the set goals

Actions on Community level will complement MS 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 the EU Commission will systematically provide assistance to the Member States.

4.1.1. Common Objectives

As already mentioned in section 3, three are the main objectives or goals: increase organ availability, make transplantation systems more efficient and accessible and improve quality and safety**.**

4.1.2. Common Indicators

Indicators are needed to monitor the performance in the different areas:

- National **Donation rates (living and deceased)** (donors per million population).
- National **multi-organ donation rates**
- **Conversion rates**
- **Number of transplant procurement hospitals**
- **Number of trasnplant coordinators per million population**
- **Number of hospitals with quality assurance programs**
- National number of **transplant procedures** per organ and million population
- Number of **organs interchanged** within the Community.
- Waiting lists
- National **survival rates**
- **Refusals to donate.**

4.1.3. National Action Plans

In order to implement each of the objectives and priority actions, Member States should prepare national action plans which will be reviewed and adapted at the mid term of the action plan (2012). These would be in two parts so as to provide both an overview of results of the actions carried out in the previous years in relation to the objectives as well as proposals for the implementation of new actions in the years to come.

On the one hand, the National Action Plans (NAP) can incorporate the above mentioned actions which have been identified as essentials in order to achieve the common goals. (See also Annex 1).On the other hand, the NAPs, can also be more country-specific and tailor-made to the specific situations in the different MS.

The National Action Plans should provide an overview of results of the actions carried out in the previous year in relation to the objectives and proposals for the implementation of new actions in the year to come.

The Action Plans will provide the basis for an overall evaluation of the success of Member States in achieving the common objectives in the area of organ donation and transplantation.

4.1.4. EU reports and benchmarking

On the basis of these reports the Commission will prepare a **synthesis report** drawing attention to common problems and identifying potential for improvements.

4.1.5. Best Practices

On the basis of the National Action Plans and the synthesis report, and applying the commonly agreed indicators (and benchmarks), the EU Commission together with the EU Member States can identify **best practices** of countries particularly good in achieving one or some of the common goals or objectives) in the area of organ donation and transplantation.

4.1.6.Peer reviews

Peer review programmes should be organised as a voluntary mutual learning process. The programmes will involve the scrutiny of specific policies, programmes or institutional arrangements presented as good practices in the various national action plans.

The aim of the peer review programme is to encourage the dissemination of good practices across Member States by assessing the effectiveness of key policies or institutions. It can serve as a useful tool to Member States to help them in the design and implementation of more effective policies

4.2. Developing and evaluating the EU Policy on organ donation and transplantation.

The Commission will play an active role in supporting and developing a common policy on organ donation and transplantation: The presentation of necessary Community legislation, the preparation of proposals for European guidelines and for promoting co-operation, exchange of best practice, evaluation and monitoring. To this end the Commission will consult widely by making appropriate arrangements including the setting up of committees and working groups (such as senior officials, Member States experts in transplantation, representatives of the social partners, patients groups and local and regional authorities, experts on particular topics and any other relevant representatives of civil society)

It is important to ensure that candidate countries are informed about this process and are involved at the earliest possible stage.. It will provide a useful preparation for accession by allowing the candidate countries to become familiar with the Community's policies and working methods. Candidate countries will be able to be involved in the process by participating in committees and/or working groups.

The activities of the Commission will include:

- Monitoring the practical application of legislation in the field, notably with a view to ensuring consistency between Member States;

- Promoting the exchange of information, experience and good practice between Member States;

- Monitoring and evaluating the implementation of the agreed objectives and priority actions, through a set of common indicators and by means of a synthesis report based on an analysis of the national reports, and including recommendations for the future development of the common transplantation policy, including the revision of the objectives.

In doing so, the Commission will ensure that this action plan is complementary and consistent with other internal and external policy areas specially when designing the strategic approach on health for the EU 2008-2017and other community initiatives relevant to this field.

4.3. Supporting measures

Co-operation will be facilitated through the second programme of Community action in the field of health (2007-2013)[6] which already envisaged on its actions 1.2.2. to "help to enhance the safety and quality of organs and substances of human origin, blood, and blood derivatives; promote their availability, traceability and accessibility for medical use while respecting Member States' responsibilities as set out in Article 152(5) of the Treaty".

During the past few years, different Community programmes have also put considerable effort into supporting organ transplantation activities. This support will continue under these different Community programmes (Research; Information Society; Justice, Freedom and security).. These programmes need to be coordinated and take into account the goals, objectives and the priority actions established in this Communication.

3. CONCLUSIONS AND FOLLOW-UP ACTIONS

By the present Communication, the Commission is seeking to set out a more detailed proposal on the implementation of an action plan in organ donation and transplantation

6

Annex 1 Specific actions proposed

GOAL 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 a potential for organ donation	
Action 1.1 Incorporating in the National Action Plans 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 coordinators 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 a potential for organ donation	
Action 2.1 Incorporate in the National Action Plans 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 the accessibility and training on specific methodology on Quality Improvement Programmes	MS action EC coordinates and monitor

Objective 2: Member States should promote the implementation of programmes of living donation following best practices.	
Priority Action 3 : Exchange of best practices on organ living donation programmes among EU Member States: Support registers of living donors	
Action 3.1 Incorporating in the National Action Plans the promotion of altruistic donation programmes for living donors, on the basis of appropriate safeguards concerning the protection of the living donors and the prevention of organ trafficking.	MS action EC coordinates and monitor
Action 3.2 Promote the development of registries for living donors to evaluate and guarantee their health and safety.	MS + EC Action
Action 3.3 Recognise and ensure the protection of living donors in the EU legal framework	MS + EC Action
Objective 3: Increase public awareness on organ donation	
Priority Action 4: Improve knowledge and communication skills of health professionals and patients support groups on organ transplantation	
Action 4.1 Incorporating in the National Action Plans the recognition of the important role of the mass media and the need to improve the level of information tothe population on these topics.	MS action EC coordinates and monitor.
Action 4.2 Promote training programmes oriented towards health professionals and , patients support groups on organ transplantation communication skills	MS + EC Action
Action 4.3 To implement at national level (competent authorities) periodic meetings with journalists and opinion leaders and management of 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

GOAL 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 Ad hoc recommendations of the committee of experts to Member States on the basis of the regular reporting to be included in the National Actions Plans.	MS + EC Action
Action 6.2 Promotion of twinning projects and peer reviews	EC Action
Action 6.3 Assessment on the use of structural funds and other community instruments for the development of transplantation systems	EC Action
Action 6.4 Promoting the development of network of centre 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.	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 on future research programmes	MS + EC Action

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

Action 8.1 Procedures for systems for offering surplus organs to other countries can be	EC + MS action

evaluated	
Action 8.2 Procedures for the exchange of organs for urgent patients and difficult-to treat patients	EC + MS action
Action 8.3 Design IT tool that could support the previous actions	EC + MS action

GOAL 3 Improving Quality and Safety

Objective 5: Improving 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 register or network of registers to follow-up on organ recipients	MS + EC Action
Action 9.3 Promote common definitions of terms and methodology to assist in determining the acceptable levels of risk in the use of expanded donors**.**	EC Action
Action 9.3 Elaboration and promotion of good medical practices on organ donation and transplantation on the basis of the results including the use of expanded donors.	EC Action

Priority Action 10: Promote a common accreditation system for organ donation/procurement and transplantation programmes

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Brussels, 28 April 2008
D(2007)

DRAFT WORKING PAPER[1]

ON A QUALITY AND SAFETY LEGAL FRAMEWORK ON DONATION, PROCUREMENT, TESTING, TRANSPORT, PRESERVATION, TRANSPLANTATION AND CHARACTERISATION OF HUMAN ORGANS

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[1] **This document does not represent an official position of the European Commission or its services. The suggestions contained in this document do not prejudge the form and content of any future proposal by the European Commission.**

1. INTRODUCTION

1.1. Over the past 50 years organ transplantation has become an established worldwide practice, bringing immense benefits to hundreds of thousands of patients. The use of human organs for transplantation has steadily increased during the last two decades. Organ transplantation is now the most cost-effective treatment for end-stage renal failure, while for end-stage failure of organs such as the liver, lung and heart; it is the only available treatment

1.2. The excellent results of transplants, in terms of life years gained and improvement in quality of life, have multiplied the indications of these therapies. Transplant procedures continue to develop and in the future may offer practical treatment for other unmet medical needs.

1.3. There are risks however associated with the use of organs in transplantation such as the transmission of diseases and it is therefore beneficial to have a safety and quality system in place to avoid potential risks and trace recipients if necessary

1.4. On 31 May 2007 the Commission adopted a Communication on organ donation and transplantation[2]. This Communication proposes the future activities of the EU in the field of organ transplantation. The Communication concludes that an appropriate and flexible European legal framework could be an adequate community response to meet the mandate provided in Article 152 (4) (a) of the Treaty.

1.5. On 6 December 2007, the European Council adopted conclusions on organ donation and transplantation. The Council recognises the importance of having high standards with respect to the quality and safety of organs for transplantation, in order to ensure a high level of protection for patients throughout Europe and invited the Commission to continue its work under the proposed action plan aimed at increasing the availability of donor organs and, in consultation with the Member States, to continue its examination of the need for an EU framework on quality and safety for human organs. It also invited the Commission to coordinate, promote and strengthen the cooperation between the Member States on organ donation and transplantation on the basis of agreed objectives and priorities.

1.6. National transplantation systems should be encouraged to increase their national donor pool. However, in transplantation medicine, it is very important that there is a good match between donor and recipient. Small Member States, have more difficulties in finding suitable matches given the smaller size of their donor pool Cooperation between Member States is therefore desirable. Some European organ exchange organisations, like Eurotransplant or

[2] Communication from the Commission to the European Parliament and the Council - Organ donation and transplantation: Policy actions at EU level, Brussels, 30.5.2007 COM(2007) 275 final.

Scandiatransplant, are already in place at community level and constitute good examples of such cooperation. However, many countries are still excluded from these arrangements.

1.7. Every year, a number of organs are exchanged between EU Member States that have entered into collaborative agreements. In the Eurotransplant area (Austria, Belgium, Germany, Luxembourg, the Netherlands and Slovenia), covering 118 million inhabitants, the average exchange rate of kidneys between partner countries was around 20% over the last five years. Cross border exchange means that the transplantation process is carried out by hospitals or professionals falling under different jurisdictions. Common quality and safety rules across the EU are therefore highly desirable and will also strengthen citizen's confidence in organ transplantation in the EU.

1.8. In particular, for the optimal treatment of specific patients (e.g urgent patients, hypersensitised patients or paediatric patients) the available organs should be able to cross borders without unnecessary problems and delays. However, national legislations in organ tansplantation differ between Member States and therefore, to ensure the same minimum standard of quality and safety for organs when cross-border exchanges take place, a common framework is needed.

1.9. From 1999 onwards, Article 152 of the Treaty has enabled the European Parliament and Council to adopt health measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives. The Community has already adopted Parliament and Council Directives on quality and safety standards for blood[3] and for tissues and cells[4].

1.10. The extensive therapeutic use of human organs for transplantation demands that their quality and safety minimises risks associated with the transmission of diseases.

1.11. The availability of organs of human origin used for therapeutic purposes is dependent on Community citizens who are prepared to donate them. In order to safeguard public health and to prevent the transmission of diseases by these organs, precautionary measures need to be taken during their procurement, transport and use.

1.12. There is a need for a Community framework in order to set quality and safety criteria with respect to the procurement, transport and use of human organs across the Community. These standards would contribute to facilitating exchanges of organs in thousands of European patients necessitating this type of therapy each year. Community provisions should ensure that human organs are of

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3 OJ L 33, 8.2.2003, p. 30–40

4 OJ L 102, 7.4.2004, p. 48–58

acceptable quality and safety. Therefore the establishment of such standards will help reassuring the public that human organs procured in another Member State nonetheless carry identical basic quality and safety guarantees as those obtained in their own country.

1.13. The risk-benefit ratio is a fundamental approach for organ transplantation. Owing to the organ shortage and the life threatening indications of organ transplants, the overall benefits of an organ transplantation are high and more risks are accepted than with blood or most tissues and cells based treatments. In this context the clinician has an important role in the decision on the acceptance of organs for transplantation.

1.14. The severe shortage of organs remains the main challenge that EU Member States face with regard to organ transplantation. Nearly 10 patients die everyday while waiting for an organ in Europe. Waiting lists are increasing faster than organ donor rates. Quality and safety requirements should take this factor into consideration so that no unnecessary barrier to organ donation is created.

1.15. The key role of national Competent Authorities in ensuring the quality and safety of this process has been emphasized**5**, as well as the importance of establishing systems for the authorisation of programmes of organ procurement and transplantation based on common quality and safety criteria**6**. This system would provide a complete list of authorised centres throughout Europe, accessible to the public and professionals.

1.16. Pre-transplant evaluation of potential donors is an essential part of solid organ transplantation. This evaluation must provide enough information to undertake a proper risk-benefit analysis by the transplant team. Risks and characteristics of the organ must be identified and documented to allow allocation to a suitable recipient.

1.17. The conditions of procurement should be authorised by the Competent Authority., The authorisation should take into account that there is a proper quality organisation and adequate staff, facilities and materials are in place. The Competent Authority should also ensure that staff responsible for the donation and staff in charge of procurement of the organ coordinate effectively. The collection of relevant information for the characterisation of the organ should be established.

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5 Council of Europe Recommendation Rec(2006)15 of the Committee of Ministers to Member States on the background, functions and responsibilities of a National Transplant Organisation (NTO).

6 Council of Europe Recommendation Rec(2004)19 of the Committee of Ministers to Member States on criteria for the authorisation of organ transplantation facilities.

1.18. Effective transportation of organs which minimises ischemic times and avoids organ damage should be established. While maintaining medical confidentiality, the organ container must be clearly labelled and must contain the necessary documentation.

1.19. The transplant system must ensure traceability from donor to recipient(s). The system must have the capacity to alert for an unexpected complication. A system must be in place to detect and investigate serious or unexpected adverse events. Many times an organ donor is also a tissue donor. Quality and safety requirements for organs shall complement and be linked with the existing community system for tissues and cells7. If required, an unexpected adverse reaction in an organ donor recipient should be traced and reported on the tissue vigilance system.

1.20. As a general principle, exchange of organs from/to third countries should be supervised by the Competent Authority. Authorisation should be granted only if equivalent standards are met .

1.21. So as to reduce the risk and maximise the benefits of the transplantation process, it is necessary that Member States operate an effective national quality program. This program should be implemented and maintained throughout the entire process, from donation to transplantation, and should cover the personnel and organisation, premises, equipment, materials, documentation and record keeping. The system should include auditing where necessary. Member States could delegate, through written agreements, the responsibility of some elements of this program to international/ regional organ exchange organisations

1.22. Personnel directly involved in the donation, procurement, testing, preservation, transport and transplantation of human organs should be appropriately qualified and provided with timely and relevant training.

1.23. It has been recommended that a professional responsible for the identification of possible deceased organ donors should be appointed in hospitals with potential for organ donation. The person should also be responsible for monitoring the donation and procurement process and for identifying and implementing improvements. **8**

1.24. As a matter of principle, organ transplantation programmes should be founded on the philosophy of voluntary and unpaid donation, altruism

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7 Directive 2004/23/EC of the European Parliament and of the Council setting high standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. OJ L 102, 7.4.2004, p.48-58

[8] Council of Europe Recommendation Rec(2005)11 of the Committee of Ministers to Member States on the role and training of professionals responsible for organ donation (transplant “donor co-ordinators”).

of the donor and solidarity between donor and recipient while ensuring anonymity of the deceased donor and the recipient(s).

1.25. This framework should respect fundamental rights and observe the principles reflected in the Charter of Fundamental Rights of the European Union and take into account as appropriate the Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on human rights and biomedicine. Neither the Charter nor the Convention make express provision for harmonisation or prevent Member States from introducing more stringent requirements in their legislation on this matter.

1.26. All necessary measures need to be taken in order to provide prospective donors of human organs with assurances regarding the confidentiality of any health-related information provided to the authorised personnel, the results of tests on their donations, as well as any future traceability of their donation.

1.27. In order to expand the donor pool it is important to explore the increase in donations from living donors**.** Living donors of organs will face risks associated both with testing to ascertain their suitability as a donor and the procedure to obtain the organ. . Complications may include medical, surgical, social, financial or psychological problems. This risk very much depends on the type of organ to be donated. It has to be recognised that living donations needs to be performed in a manner that minimizes the physical, psychological and social risk to the individual donor and does not jeopardise the public trust on the healthcare community. The donation decision should be performed in an environment that enables the potential living donor to decide in an autonomous manner[9].

1.28. The clinical use of organs of human origin for transplantation is constrained by limited availability. Therefore it would be desirable that the criteria for allocating these organs are defined in a transparent manner, on the basis of an objective evaluation based on medical need and other factors.

1.29. The legal framework will be complemented with a Community action plan on strengthened coordination between Member States on organ donation and transplantation.

1.30. It is necessary that the best possible scientific advice is available to the Community in relation to organ donation and transplantation; in particular to assist the Commission in adapting the provisions of this legal framework to advancing scientific and technical progress.

[9] Consensus Statement of the Amsterdam Forum on the care of living kidney donor.

2. QUALITY AND SAFETY PRINCIPLES

The following sections will provide a basis for the discussion of the future content of a possible EU instrument on quality and safety. It attends to consolidate the basic quality and safety principles into more detailed provisions:

2.1. GENERAL PROVISIONS

Rationale of the chapter of general provisions

This chapter establishes the objective and the scope of the quality and safety framework. The objective based on Article 152 of the Treaty is to ensure high quality and safety standards for human organs and a high level of protection of human health. The scope should cover the whole process from donation to transplantation, respecting at the same time the responsibility of Member States for the organisation and delivery of health services and medical care.

This chapter includes the definitions to be used in the quality and safety framework, which are based on previous pieces of community legislation (Directive 2004/23/EC) or in recognised international bodies (UNOS, CoE).

It also presents the principle of national authority(ies) which is a basic element in the EU quality and safety framework; these competent authorities are responsible for the implementation of the quality and safety framework.

Finally, it establishes the principle of minimum harmonisation inherent to the legal basis of Article 152. This legal framework establishes minimum requirements that Members States could maintain or reinforce with more stringent protective measures.

2.1.1. Objective

This EU quality and safety framework lays down standards of quality and safety for human organs intended for transplantation[10].

2.1.2. Scope

The provisions of this EU quality and safety framework should apply to the donation, procurement, testing, preservation, transport, distribution, transplantation and characterisation of human organs intended for transplantation[11].

[10] A recital clarifying that quality and safety standards shall take fully into account the context of shortage of organs should be included.

[11] A recital explaining the importance of having in place a allocation system should be included

2.1.3. Definitions[12]

For the purposes of this EU quality and safety framework:

a) 'allogeneic use' should mean organs removed from one person and applied to other. (EU + CoE)

b) 'allocation' means assignment and distribution of human organs (CoE) ; The process of determining how organs are distributed**.** Allocation includes the system of policies and guidelines, which ensure that organs are distributed in an equitable, ethical and medically sound manner. (UNOS)

c) 'donor' means every human source, whether living or deceased of human organs. (EU + CoE)

d) 'living donor' means a living person who donates an organ (or part of an organ) for transplantation. (EU + CoE)

e) 'distribution[13]' means transportation and delivery of human organs for use in recipients. (EU + CoE)

f) 'Domino Transplant' means a procedure in which an organ is removed from one transplant candidate and immediately transplanted into a second patient, with the first patient receiving a new organ from a deceased donor. (UNOS)

g) 'organ' means a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with an important level of autonomy. (EU + CoE)

h) 'organ procurement team' means the health care professionals involved in any of the activities necessary for organ procurement. (EU)

i) 'transplantation centre' means a health care establishment or a unit of a hospital or another body which carries out transplantation of human organs.(EU)

j) 'organ characterisation' means the collection of the relevant information on the characteristics of the organ and the donor needed to undertake an adequate risk assessment to minimise the risks for the recipient and to optimise the allocation of the organ. (new)

k) 'procurement' should mean a process by which the donated organs become available. (EU + CoE)

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[12] Some definitions were proposed to be added: donation, domino transplantation, split transplantation, establishment and allocation.

[13] It is important to clarify the differences between distribution and allocation in a recital. A better definition of distribution and a new definition of allocation are needed.

l) "procurement organisation" means a health care establishment or a unit of a hospital or another body that undertakes the procurement of human organs. (EU)

m) 'preservation' should mean the use of chemical agents, alterations in environmental conditions or other means during processing to prevent or retard biological or physical deterioration of human organs from the procurement until the transplantation. (EU + CoE)

n) 'recipient': means a person who receives a transplant. (UNOS)

o) 'serious adverse event'[14] should mean any unexpected occurrence associated with the procurement, testing, preservation and distribution of human organs that might lead to the transmission of a communicable disease, to death or life-threatening, disabling, or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity. (EU + CoE)

p) 'serious adverse reaction' should mean an unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of human organs that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity. (EU + CoE)

q) 'standard operating procedures' (SOPs) means written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end product. (EU)

r) 'transplantation' should mean the process of reconstituting a function by transferring equivalent organs to a recipient. . (EU + CoE)

s) 'traceability' means the ability to locate and identify the organ from procurement to distribution to the recipient or disposal, which implies the ability to identify the donor and the establishment where the organ is procured, and the ability to identify the recipient(s) at the medical facility/facilities applying the organ to the recipient(s); traceability also covers the ability to locate and identify all relevant data relating to products and materials coming into contact with those organs. (EU + CoE)

2.1.4. Implementation

1. Member States should designate the national Competent Authority or authorities responsible for implementing the requirements of this EU quality and safety framework.

[14] Definitions (or the content of the Article) of serious adverse and events should be better clarified to avoid unnecessary over reporting.

2. This EU quality and safety framework should not prevent a Member State from maintaining or introducing more stringent protective measures that comply with the provisions of the Treaty.

2.2. OBLIGATIONS ON MEMBER STATES AUTHORITIES

Rationale of the chapter of obligations

This chapter describes the main mechanisms that Member States should put in place.

1- The first of the mechanisms is to establish a structure in all Member States for the authorisation of activities. Two type of authorisations are envisaged.

A) The first one refers to the authorisation of the conditions of procurement ; this process should include the characterisation of the organ/donor and the conditions of the retrieval/preservation of the organs by the different medical/surgical team.

B) The last one is for the transplantation programmes where this legal framework is limited to establish the need of an authorisation, but under national rules.

The document also should establish authorisation of import/export from/to third countries (non EU countries)

2- The quality and safety framework will establish a register of centres authorised for the procurement and transplantation of organs, this register should be accessible at EU level. The framework will also request Member States to collect relevant activity data.

3- The quality and safety framework will establish the general principles of transport, traceability and reporting of serious adverse events and reactions. Member States have the duty to ensure that mechanisms are in place for the protection of donors and recipients. This should ensure rapid investigation of any unexpected incidents occurring in relation to the transplantation services, so timely corrective and preventive actions can be taken.

4- Finally, this chapter describes the basic information that should be taken from the organ donor for each of the organs and the need to establish a system responsible for transmitting this information to undertake an adequate risk assessment to minimise the risks for the recipient and to optimise the allocation of the organ.

2.2.1. Supervision of procurement of human organs.

1. Member States should ensure that the procurement of human organs are carried out by persons with appropriate training and experience and that they take place in conditions that have been accredited, designated, authorised or licensed by a competent authority for the purpose of those activities.

2. The Competent Authority or Authorities, having verified that the conditions of procurement comply with the requirements referred in this legal framework, should accredit, designate, authorise or license these activities and indicate which conditions apply.

2.2.2. Organ characterization

1. The Competent Authority or Authorities should ensure that the information on the quality and safety characteristics of all donated human organs are obtained in accordance with the requirements referred by comitology procedure

2. The Competent Authority or Authorities should ensure that there is a system in place to transmit the information on organ characterisation, obtained in accordance with paragraph 1, to the organisations responsible for transplantation, in order that the transplant team can undertake the appropriate risk assessment.

3. Organisations responsible for transplantation should verify and record the fact that the information received complies with the requirements referred to in paragraph 1.

4. The procedures for transmitting the information on quality and safety characteristics of human organs, obtained in accordance with paragraph 1, when the organ is distributed to other Members States, should be established comitology procedure .

2.2.3. Accreditation, designation, authorisation or licensing of organ transplantation

1. Member States should ensure that all establishments where activities of transplantation of human organs are undertaken have been accredited, designated, authorised or licensed by a competent authority for the purpose of those activities.

2. The Competent Authority or Authorities in keeping with their national legislation, accredit, designate, authorise or license the establishment and indicate what activities it may undertake and what conditions apply.

3. Member States shall, upon the request of another Member State or the Commission, provide information on the requirements for in authorisation of transplantation establishments.

2.2.4. Exchange of human organs[15] with third countries

1. Member States should take all necessary measures to ensure that all exchanges of human organs from or to third countries are authorised by the Competent Authority or Authorities, and that these organs can be traced from the donor to the recipient and vice versa. The Competent Authority and the establishments that receive or send organs from or to third countries should ensure that they meet standards of quality and safety equivalent to the ones laid down in this EU quality and safety framework.

2. The Competent authority may establish written agreements with international organisations/organ exchange organisations to carry out the activities under 2.2.4.1.

[15] It is needed to check with Legal Service if this includes EEA countries.

The Competent authority should evaluate and select this international organisation on the basis of their ability to meet the standards laid down in this framework.

2.2.5. Register of establishments and reporting obligations

1. Establishments should keep a record of their activities, including the number of donors, and the types and quantities of organs procured and transplanted, or otherwise disposed. They should submit to the competent authority or authorities an annual report on these activities. This report should be publicly accessible.

2. The Competent Authority or Authorities should establish and maintain a publicly accessible register of establishments where procurement or transplantation of human organs takes place.

3. Member States and the Commission should establish a network linking the national establishment registers.

2.2.6. Traceability

1. Member States should ensure that all organs procured and distributed on their territory can be traced from the donor to the recipient and vice versa.

2. Member States should ensure the implementation of a donor identification system able to identify each donation and each of the organs associated with it.

3. All organs must be identified with a label that contains the relevant information for traceability and characterisation of the organ or references allowing a link to this information.

4. The Competent Authority or the establishments should keep the data necessary to ensure traceability at all stages. Data required for full traceability should be kept for a minimum of 30 years after donation. Data storage may also be in electronic form.

5. In case the organ is allocated cross border to another Member State the procedure to ensure full traceability at Community level should be complemented by the Commission through comitology procedure.

2.2.7. Notification of serious adverse events and reactions

1. Member States should ensure that there is a system in place to report, investigate, register and transmit information about serious unexpected adverse events and reactions which may influence the quality and safety of human organs and which may be attributed to the procurement, testing, and distribution/transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to the procurement, testing and transport/distribution of the organ.

2. The Competent Authority or Authorities should ensure that an accurate, rapid and verifiable procedure is in place which will enable it to recall from distribution any organ which may be related to an unexpected adverse event or reaction.

3. The Competent Authority or authorities should ensure that there is a connection with this system and the reporting system of human tissues and cells established in Directive 2004/23/EC.

4. The procedures for ensuring reporting serious unexpected adverse events and reactions in case of cross border exchanges at Community level should be complemented by the Commission through comitology.

2.3. DONOR PROTECTION

Rationale for the chapter of donor protection

This chapter try to address a number of complex and sensitive issues as far as is permitted by the legal basis of Article 152, which is limited to quality and safety.

Donation should be voluntary and altruistic with legal and ethical contexts clearly defined, both for ethical and public health reasons.

Data from donors and recipients should be protected, provided that traceability is ensured. Anonymity should aimed at except in the case of a living donor with a close relationship to the recipient.

Organ retrieval is only allowed if some form of consent is available. This is also reflected in international guidelines; according to the additional protocol to the Convention of Biomedicine of the Council of Europe concerning Transplantation of Organs and Tissues of Human Origin16. Member States should ensure that there is a legal basis for ensuring valid consent or objection to organ donation.

The protection of the living donor is specifically addressed in this chapter.

2.3.1. Principles governing organ donation

1. Member States should ensure voluntary and unpaid donations of human organs.
2. Member States should take all necessary measures to ensure that any promotion and publicity activities in support of the donation of human organs comply with guidelines or legislative provisions laid down by the Member States. Such guidelines or legislative provisions should include appropriate restrictions or prohibitions on advertising the need for, or availability of, human organs with a view to offering or seeking financial gain or comparable advantage.

2.3.2. Consent

1. The procurement of human organs should be authorised only after all mandatory consent or authorisation requirements in force in the Member State concerned have been met.
2. Member States should, in keeping with their national legislation, take all necessary measures to provide appropriate information to citizens about the procedure of consent for organ donation; including how this procedure applies to non nationals.

16 http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=186&CM=8&DF=8/29/2006&CL=ENG

2.3.3. Data protection and confidentiality

1. Member States should take all necessary measures to ensure that all data to which third parties have access, have been rendered anonymous so that neither donors nor recipients remain identifiable.

2. For that purpose, they should ensure that:

   (a) data security measures are in place, as well as safeguards against any unauthorised data additions, deletions or modifications to donor files or deferral records, and transfer of information,

   (b) procedures are in place to resolve data discrepancies, and

   (c) no unauthorised disclosure of information occurs, whilst guaranteeing the traceability of donations.

3. Member States should take all necessary measures to ensure that the identity of the recipient(s) is not disclosed to the family of the deceased donor and vice versa without prejudice of legislation in force in Member States.

2.3.4. Protection of the living donor

1. The living donor should be given appropriate and independent information as to the purpose and nature of the donation, and to the consequences and risks. The information should be supplied in advance and should be as accurate as possible.

2. Living donors must be selected on the basis of their health and medical history, including psychological evaluation if deemed necessary, and should be undertaken by a qualified and trained professionals. This assessment must include relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as the possibility of transmitting diseases or health risks to themselves.

3. .Member States should ensure the health care coverage related to the donation of the living donor before, during and after the procedure, ensuring the living donor has long term access to the health care system

4. Member States should keep a register to followup living donors from all authorised establishments.

PROVISIONS ON THE QUALITY AND SAFETY

Rationale for the chapter of provisions on the quality and safety

This chapter focus in the quality program that competent authorities should put in place to ensure the basic standards.

1- Establish a quality program is a basis prerequisite. ,The characteristics of such a program should be defined at Member States level, however it should be based on the principles of good practice and clearly define standard operational procedures and comply with the requirements of this quality and safety framework . The management of the system could be located at different levels, the establishments or procurement organisations and/or the competent authorities, or under the umbrella of international organisations.

2- As an element of this program the second main element is having a system of auditing and control measures. The system should evaluate in a regular basis the procedures and the activities carried out that are relevant for the quality and safety.

3- This chapter establish also requirements for the personal at the establishments, the conditions of procurement and the transport of human organs under this quality program.

2.3.5. Quality national programs

1. Member States should take all necessary measures to ensure that the Competent Authority put in place and update a national quality program based on the principles of good practice which establishes standardised procedures. This programme should be implemented and maintained throughout the entire process, from donation to transplantation, to ensure the compliance of the quality and safety requirements laid down in this framework.

2. The Competent authority may establish written agreements with international organisations to carry out activities under the national quality programs. The Competent authority should evaluate and select these international organisations on the basis of their ability to meet the standards laid down in this framework.

2.3.6. Control measures

1. Member States should ensure that the Competent Authority or Authorities and/or the establishments put in place appropriate control measures to ensure compliance with the quality and safety requirements, including auditing the activities where relevant.

2. These control measures should evaluate and verify in a regular basis the procedures and the activities carried out that are relevant for the requirements of the quality and safety framework;

2.3.7. Personnel

1. Personnel directly involved in activities relating to the donation, procurement, testing preservation and distribution of human organs should be qualified to perform such tasks and should be provided with the relevant training.

2. The organisational structure and operational procedures should be appropriate to the activities for which accreditation/designation/authorisation/licensing is sought; there must be an organisational chart which clearly defines job descriptions, accountability and reporting relationships.

2.3.8 Conditions of procurement

1. The Competent Authority or Authorities should ensure that the information on the quality and safety characteristics of all donated human organs are obtained in accordance with 2.2.2.

2. Procurement of human organs should be carried out by persons who have successfully completed a training programme as specified in 2.3.7

3. Procurement shall take place in appropriate facilities, following procedures that minimise bacterial or other contamination of procured human organs. The premises should attain normal standard for operating theatres, with limited access, personnel should be appropriately dressed for sterile operations, wearing sterile gloves, hat and facemask.

4. Procurement materials and equipment shall be managed in accordance with relevant national and international regulation, standards and guidelines covering the sterilisation of medicines and medical devices. Qualified, sterile instruments and procurement devices shall be used for organ procurement.

5. As part of the quality program mentioned in 2.3.5 there should be standardised protocols for the verification of:

(a) donor identity;

(b) the details of donor or donor family consent or authorisation according with national rules;

(c) the completion of the organ characterisation

(d) Procedures for procurement, preservation packaging and labelling of human organs

6. Where appropriate, the staff and equipment necessary for body reconstruction of deceased donors shall be provided. Such reconstruction shall be completed effectively.

2..3.9 Transport of human organs

1. The Competent Authority should ensure that as part of the quality program there are standarised protocols in place to maintain the integrity of the organ and minimise the transit time.

2. If transportation is within the same hospital should be designed to keep the organ in good condition .

3. For transportation outside the hospital, the shipping container should conform to national regulations and must be labelled with at least the following information:

(a) identification of the originating establishment, including an address and phone number;

(b) identification of the organisation responsible for transplantation, including address and phone number;

(c) a statement that the package contains a human organ and HANDLE WITH CARE;

(d) recommended transport conditions (e.g. keep cool, in upright position, etc.);

(e) safety instructions/method of cooling (when applicable).

4. The receiving facility should verify that the indicated storage temperature and proper condition of the shipped organ has been maintained.

2.4. COOPERATION BETWEEN MEMBER STATES, EXCHANGE OF INFORMATION AND REPORTS

Rationale for the chapter of provisions on cooperation between Member States This chapter focus in measures to can promote cooperation between Member States in order to share experience and best practices.

2.4.1. Cooperation between competent authorities

1. The Commission should hold regular meetings with the competent authorities designated by the Member States, delegations of experts on organ transplantation, European organ exchange organisations and other relevant parties to exchange information on the experience acquired with regard to the implementation of this quality and safety framework.

2. The Commission should adopt specific measures necessary for the implementation of these objectives and for achieving the sharing information and communication technology systems between Member States, while respecting the principles of privacy and protection of personal data in accordance with the applicable law.

2.4.2. Reports

1. Member States should report to the Commission on the activities undertaken in relation to the provisions of this EU legal framework, and on the experience gained in implementing this EU quality and safety framework.

2.5. COMMITTEES AND TECHNICAL REQUIREMENTS

1. The Commission should be assisted by a Regulatory Committee.

2. The Commission may consult the relevant scientific committee(s) when defining or adapting the following technical requirements and their adaptation to scientific and technical progress:

(a) requirements for ensuring traceability at community level for cross border exchange at community level.,

(b) requirements for serious adverse events and reactions reporting for cross border exchanges at community level

(c) requirements for organ characterisation