COMMISSION OF THE EUROPEAN COMMUNITIES

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accompanying the

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on standards of quality and safety of human organs intended for transplantation

and the

COMMUNICATION FROM THE COMMISSION

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

Summary of the Impact Assessment

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SUMMARY OF THE IMPACT ASSESSMENT[1] IMPROVING ORGAN DONATION AND TRANSPLANTATION IN THE EUROPEAN UNION

1. PROBLEM DEFINITION

Due to rapid advances in transplantation medicine, the use of human organs for transplantation has steadily increased during the past decades. Organ donation has a very high potential of saving lives and increasing the quality of life for patients. This potential can only be realised, however, when a sufficient number of organs is available for transplantation, when there are adequate quality and safety measures in place to reduce the risks of diseases being transmitted, and when processes are organised efficiently and are accessible to all those who are in need.

1.1. Organ availability

Currently, demand for organs exceeds their availability in all Member States and demand increases faster than organ donation rates in most Member States. While there is an increasing demand for organs, the availability of organs varies widely between the Member States, ranging from 33.8 deceased donors per million of population in Spain to 1 deceased donor per million population in Romania. Only Spain and few others Member States have succeeded in increasing significantly the number of donors. It has been proven that these increases are linked to the introduction of organisational practices.

Living donation rates also differ substantially between Member States, and it seems that not all countries realise their potential for living donation.

The importance of organisational aspects of organ procurement and the large differences in practices and performances across Member States show a clear benefit of exchanging best practices between the Member States of the European Union.

1.2. Quality and Safety in organ transplantation

Organ transplantation is a potentially life saving treatment, which nevertheless involves substantial risks to the patients. These risks emanate from the quality and matching characteristics of the organ as well as the medical treatment received.

The use of organs in therapy poses a risk of infectious diseases being transmitted to the organ recipient. Transplantation can also lead to the transmission of different types of cancers. In addition, the quality and safety of organs can be at risk due to organ damage during the procurement process. To reduce these risks, most transplantation systems apply quality and safety procedures throughout the complex donation process. Currently quality and safety standards differ widely across Member States.

1.3. Enhancing the efficiency and accessibility of transplantation systems

The exchange of organs between Member States is already common practice between them. There are however large differences between the number of organs exchanged across borders between Member States which set up bodies and rules for the international exchange of organs such as Eurotransplant and Scandiatransplant and the other Member States.

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[1] On the basis of SEC(2005) 791 of 15 June 2005 (Impact Assessment Guidelines).

The differences in exchange rates indicate that the full potential of exchanging organs has not yet been reached. This is problematic as the cross border exchange of organs has clear benefits. Given the need of matching between donor and recipient, a large donor pool is important to cover the needs of all patients on the waiting lists. If there is no exchange of organs between Member States, then recipients that need an infrequent match will have very low chances of receiving an organ, while at the same time donors are not considered because there is not a compatible recipient in the waiting lists. This is particularly true for difficult to treat patients (paediatric, urgent or hyper-sensitised patients that require very specific matching) and small Member States. The mobility of potential organ donors and recipients is the second major challenge for the current quality and safety frameworks, after organ shortage. Evidence shows that more and more people might become organ donors while residing in another Member State. To ensure that organs available for therapy are not wasted, it is important that there are no legal barriers to the use of these organs and that the families of these donors have trust in the donation system so that they do not refuse donation.

2. SUBSIDIARITY

Article 152 of the EC Treaty provides a clear legal basis for the initiatives proposed An EU measure in the area of organ transplantation and donation can be reconciled with the principle of subsidiarity on the following grounds:

1) The European Community has a clear opportunity and obligation to implement binding measures laying down high standards of quality and safety for the use of blood, organs, and substances of human origin.

2) European Community action is likely to contribute to public value by providing a platform for implementation and mutual learning which combines standardisation of reporting with diversity of service.

3. THE POLICY OBJECTIVES

Ultimately, the strategic goal is to achieve a high standard of human health protection. In the area of organ donation and transplantation, this goal can be broken down into three objectives to tackle current and future shortcomings and to guide European policy: 1) increasing organ availability; 2) enhancing the efficiency and accessibility of transplantation systems: and, 3) improving quality and safety.

4. THE POLICY OPTIONS

Option 1: Continuing Status quo

Under this option, the European Commission would continue with its current activities in the field of organ donation and transplantation, which involves predominantly sponsoring research and pilot programmes in this field and participating in international cooperation such as in the Council of Europe.

Option 2: Action plan

This option proposes a non-regulatory approach establishing a European Action Plan on Organ Donation and Transplantation for the period 2009-2015 which sets out a cooperative approach between Member State based on a set of priority actions. This approach is based on

the identification and development of common objectives, agreed quantitative and qualitative indicators and benchmarks, regular reporting and identification of best practices.

Option 3: Action plan + "flexible directive"

Option three combines the Action Plan already described with a "flexible" Directive. The regulatory approach of this directive will be very much a framework approach, ensuring that national legislation is put in place to deal with key aspects of organ donation and transplantation but without prescribing detailed policy measures.

The Directive will ensure that the quality and safety structures are in place. These will facilitate the conditions for cross border exchanges and ensure a basic level of quality and safety for patients.

Option 4: Action plan + "stringent directive"

Option 4 will combine the Action Plan described under Option 2 with a stringent Directive. This stringent Directive will be modelled after the Tissue and Cells Directive and will therefore contain detailed regulation about the quality and safety systems Member States have to put in place, leaving little national discretion in transposing the Directive. As mentioned above, Option 4 provides for a stricter regulatory approach. This option will include a more complex accreditation process for procurement sites, including regular inspections which entail the need to put in place a specific inspection structure. It requires also a detailed quality system in place in every donation site. The Directive will lay down exclusion criteria for donors following the same approach followed in the Blood and Tissues and Cells Directives.

5. ASSESSMENT OF IMPACTS: COMPARING THE OPTIONS

5.1. Health Impacts

The key health impacts emanate from an increase in donation rates (increase on health expectancy and quality of life for the patients in need) and reduced risks to patients. The policy options are likely to increase donation rates in Europe. In addition, the policy options are likely to increase cross border exchange of organs, which result in clear health benefits for paediatric, highly sensitised and urgent patients.

Option 1 would not change the current unsatisfactory status quo, with diverging quality and safety standards across Europe and, an undeveloped potential for cross border exchange of organs Option 2 can create substantial health gains though increases in donation rates. These gains could range normally from 0-113.000 QALYs gained. Nonetheless these increases are uncertain as the option allows for a high level of discretion in national implementation, therefore an estimation of 60,000 QALYs seems more realistic. Option 2 will not have an impact on the quality and safety of organs, but will for instance remove possible disincentives to become a living donor by ensuring access to health care for living donors; without however including provisions for eventually necessary social care.

Option 3 and 4 supplement Option 2 through legal standards and will have a more certain effect on donation rates to the degree that positive changes will become mandatory. It is likely that these options ensure at least a modest increase of 2.600 organs being transplanted, resulting in 39.000 saved life years or 37.000 more QALYs; we could assume that the average QALYs gained will be superior, reaching 90.000 QALYs. In addition, Option 3 and 4 will establish common quality and safety standards across the European Union, which will reduce

risks to patients and stimulate cross border exchange of organs. Nonetheless, Option 4 in turn by ensuring stringent quality and safety standards across the European Union might lead to substantial difficulties in implementation for the relevant facilities and therefore might even have a negative impact on donation rates for some of them.

5.2. Social impacts

Increasing organ transplantation will result in positive social impacts for organ recipients and donor families. Evidence shows that organ transplantation increases the possibilities for patients to participate in social and working life. In general, organ transplantation has a positive effect on the Quality of Life of organ recipients. Thus, the different options will generate additional social benefits, depending on the additional transplantations achieved from increased donation rates.

European action can be expected to contribute to increasing trust and confidence in organ donation and transplantation systems, by establishing common quality and safety standards, increasing public awareness, and improving processes to deal with the relatives of deceased donors. However, the available evidence on such social impacts such as social participation and improved standards of living do not allow for an adequate assessment of the precise impacts in order to compare the options.

Given the social impacts of increasing donation rates and the importance of having more robust donation and transplantation processes, we would expect the highest social benefits from option 3 and 4, which increase donation rates with higher certainty and are more likely to enforce standards of good processes.

5.3. Economic Impacts

The analysis of the policy options suggest that Options 2 to 4 can lead to substantial economic benefits across the European Union, although Member States will have to invest in national infrastructures of organ donation and the improvement of processes to realise these gains. Nonetheless, the available evidence does not allow for the production of detailed cost estimates for Member States. The economic benefits arise primarily from saved treatment costs as transplanted kidneys replace dialysis treatment. Scenarios developed see a potential of saving up to €1.2 billion in treatment costs, and reaching productivity gains of up to €2.4 billion.

Policy Option 1 continues the *status quo* and is expected not to create any additional costs or economic benefits. Option 2 could generate substantial economic benefits of up to €1.2 billion savings in treatment costs and an additional productivity impact of €3.6 billion at low costs for process and infrastructure improvement. Due to the voluntary nature of the Action Plan, it is recognised that the impacts are highly uncertain because the extent of implementation by Member States is to a large extent unknown.

Policy Option 3 combines the Action plan with a flexible Directive. Option 3 will lead to substantial costs to implement national registers, reporting activities and a national vigilance system. However, due to the mandatory character of the option, we see cost savings and productivity to occur under less uncertainty, at a range between €132 million and €1.2 billion for cost savings, and €460 million and €2.4 billion for productivity impacts. Finally, Option 4 is expected to bring the same economic benefits as Option 3, however at higher implementation costs, as Member States have less freedom to use existing systems and devise tailor-made national solutions.

6. IDENTIFYING A PREFERRED OPTION

In weighing the available evidence, Option 3, which combines an Action Plan with a flexible Directive creating a European framework regulation for quality and safety, will help achieve the objectives at the best cost benefit ratio.

The least costly option, Option 2, will not be sufficient to create a robust quality and safety framework and will thus not help achieve the third objective. In addition, the potential positive health and economic impacts are more uncertain than for the other three options. Even more so than Option 3 and 4, Option 2 relies on the commitment of Member States to voluntarily change organisational structures, improve processes and invest into organ donation and transplantation.

Option 4 in turn will ensure the most stringent quality and safety standards across Europe, which comes however at the risk of creating unnecessary administrative burden. These requirements while fully justified in the tissues and cells field, could when it comes to organs disincentive donation activity in small and medium hospitals by creating unnecessary administrative burden, whereas the objective should be to increase the involvement of these actors in the donation process

A strict regulatory approach might lead to substantial difficulties in implementation and might even have a negative impact on donation rates for some facilities. In addition, Option 4 can be expected to have the highest overall implementation costs, as even countries with already well established donation and transplantation systems will need to change some of their infrastructures and processes to comply with EU prescriptions. Nevertheless, Option 4 will also have also substantial economic benefits through saved treatment costs and the productivity impacts of longer life expectancy.

There is however a clear need to ensure that the conditions of procurement comply with basic quality and safety standards and to designate those procurement sites entitled to carrying out these activities. Option 3 will achieve these objectives tailoring the quality and safety requirements to this particular field.

In addition Option 4 would also include, as in the Tissues and Cells legal framework, suitability criteria for the donor (including exclusion criteria of donors). In the contrary, Option 3 will introduce a new approach by ensuring a complete characterisation of the organ without prejudging the suitability of the donor and therefore respecting the clinical decision that has to take into account the condition of the recipient. This will allow the transplant team to undertake the appropriate (and fully informed) risk assessment.

This approach is key to respecting the use of expanded donors (donors that are not in theory ideal) for specific recipients in waiting list (e.g. very aged donors can be used to aged recipients in particular circumstances). In the contrary Option 4 could restrict the potential of increasing organ donation by diminishing the use of "expanded donors". Option 3 provides enough flexibility to the transplant team to undertake the appropriate risk assessment and balance it with the potential benefit.

Overall, Option 3 will be best suited to achieve the objectives of increasing donation rates, making transplant systems more accessible and efficient and ensuring quality and safety standards. By allowing a certain degree of flexibility for the Member States, this option reduces implementation costs and administrative burden, while at the same time safeguarding minimum quality and safety standards. The introduction of a flexible set of binding requirements on quality and safety will not only cover properly the third objective but will

also trigger and stimulate the objectives under the Action Plan. It is likely to increase donation rates which would result in substantial benefits for patients as well as substantial cost savings for the national health systems.