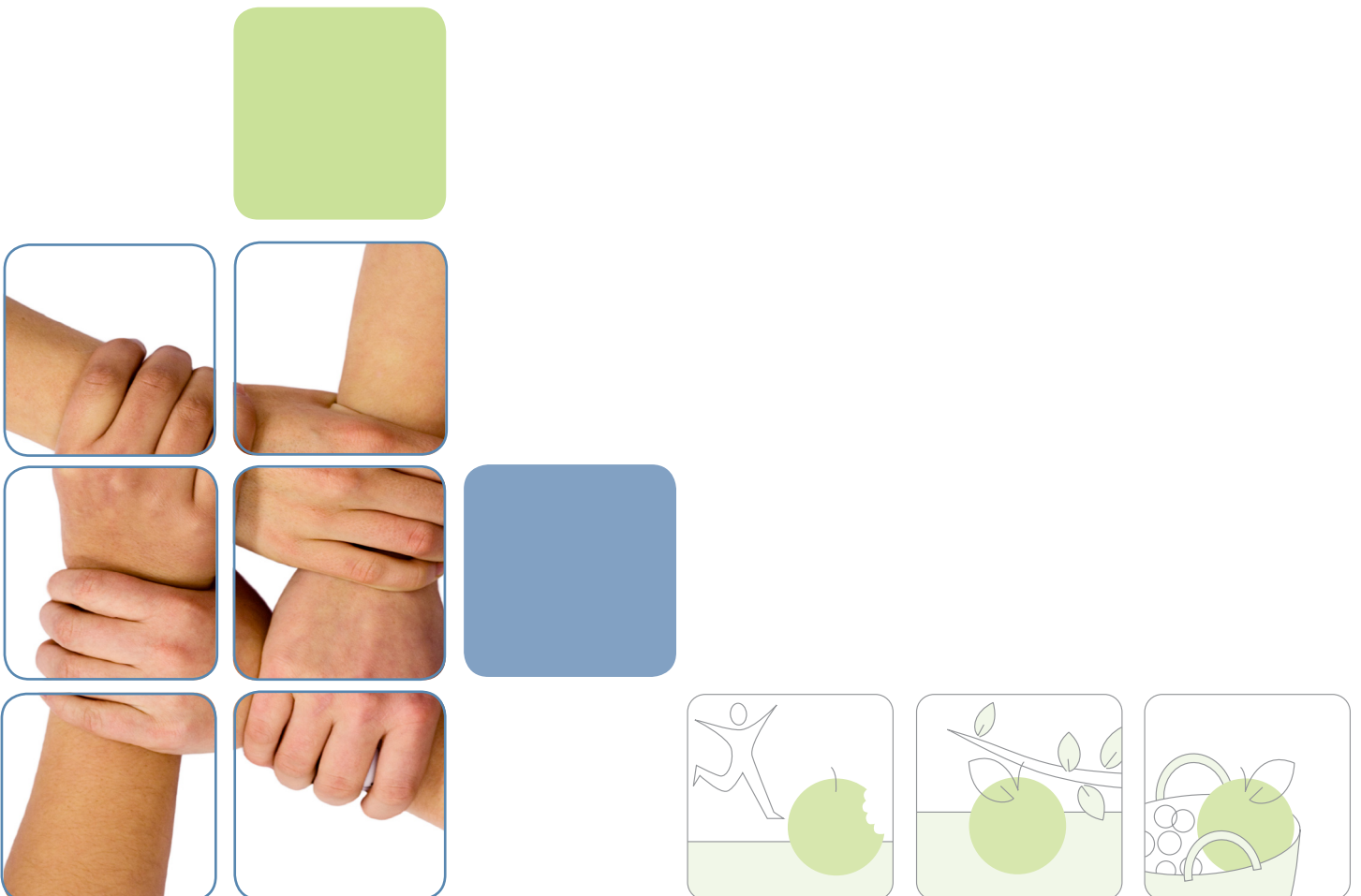


Report on the Open Consultation : Policy options for organ donation and transplantation at EU level





EUROPEAN COMMISSION



Report on the Open Consultation: Policy options for organ donation and transplantation at EU level

Directorate C - Public Health and Risk Assessment
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1. INTRODUCTION

In June 2006, DG SANCO launched an open consultation on organ donation and transplantation. Stakeholders were invited to express their position on the basis of a Consultation document on "Organ donation and transplantation: Policy options at EU level". The aim of the consultation was to identify the main problems encountered in organ donation and transplantation, to invite ideas on EU initiatives that could help to solve these problems, and to determine the extent to which measures should be taken at Community level.

In the consultation, 3 possible scenarios were outlined for future EU action with regard to organ donation and transplantation.

This document summarises the contributions made by stakeholders to the public consultation that ran from June to September 2006.

The Commission received 73 contributions. Many of them, in particular the ones from regulators, the medical community and the patients or donors associations, were results of wider consultation among their stakeholders.

Contributions were received from 18 Member States (Austria, Belgium, France, UK, Czech Republic, Finland, Sweden, The Netherlands, Denmark, Germany, Ireland, Italy, Spain, Portugal, Latvia, Hungary, Malta, Slovenia and Poland), Norway, Switzerland, Georgia, the US and Argentina. A full listing of all parties providing comments is at the end of this document.

The participants can be divided into 5 categories:

- Patient or donor associations (15 contributions);
- Transplantation professionals and scientific associations (26 contributions)
- Governmental bodies, national ministries, national agencies of transplantation; regional representatives, international institutions and organ exchange organisations (24 contributions);
- Individuals (4 contributions);
- Others (4 contributions).

Contributions are also published on the DG SANCO website. The valuable information provided will be used to develop the Commission's further action in this field.

2. OPTIONS DESCRIBED IN THE CONSULTATION DOCUMENT

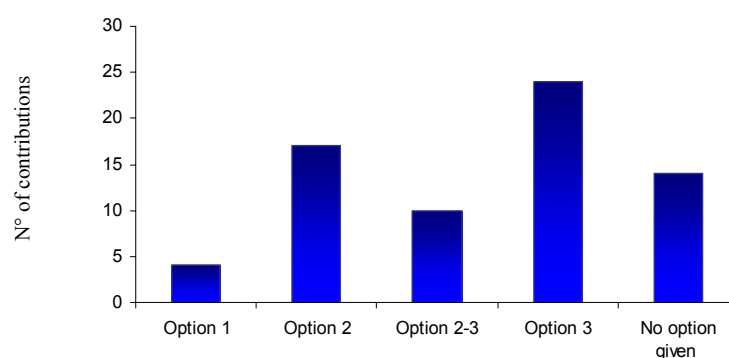
The consultation outlined 3 scenarios for future EU action:

1. To continue the work under existing Community programmes, without further coordination (Option 1).
2. To promote active coordination between Member States on organ quality, safety and availability (Option 2).
3. To strengthen coordination between Member States, consider minimum harmonisation on quality and safety to complement and reinforce these actions through a directive, and in addition an initiative on organ trafficking (Option 3).

3. SUMMARY OF THE REPLIES TO THE CONSULTATION

- i. The vast majority of respondents welcomed the Commission's consultation paper, the opportunity to submit contributions, and explicitly supported the outlined objectives. The need for an EU action in this field was emphasised. Broadly speaking, most of the contributors agreed with the key principles and concepts underlying the Commission's consultation document.
- ii. There was a consensus on the importance of ensuring the quality and safety of organs for transplantation at EU level. The current shortage of organs was also acknowledged.

Diverse opinions were expressed on what should be the best approach to solve the problem. Option 3 (above) attracted the widest support. However, an important number of respondents considered Option 2 to be the most preferable.

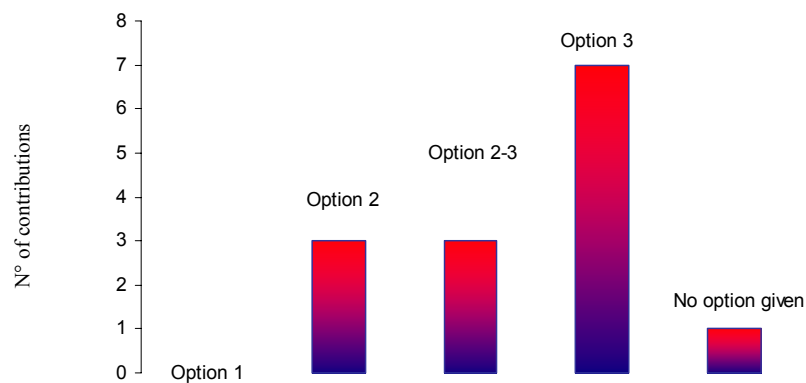


Some considered Option 2 as a “phasing in period”, after which, in the light of the work done through the coordination method, the introduction of legislative instruments could be considered. This has been named as "Option 2-3" and it incorporates the responses in favour of Option 2 plus an initiative on organ trafficking, but not a quality and safety directive.

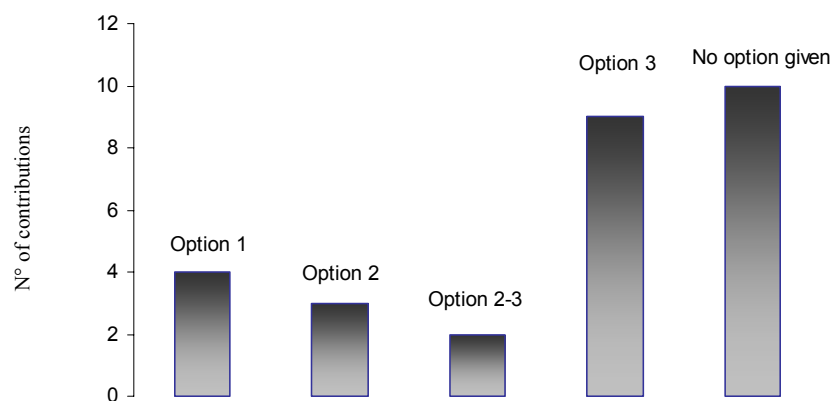
Many respondents did not express their preference for a particular option but made interesting suggestions on different types of activities that could be undertaken at Community level.

The majority of patients, donor associations and professional stakeholders supported the third option.

Patients and donor associations

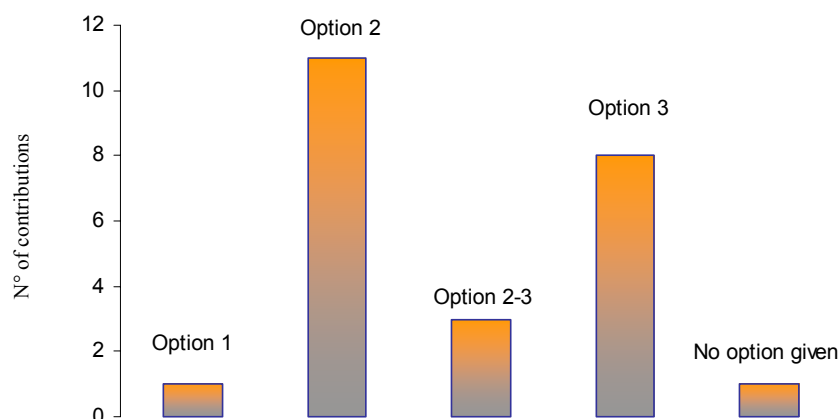


Professionals and scientific associations



Many professional or scientific associations provided a good number of comments on possible initiatives without selecting any specific option.

Organ exchange organisations, national agencies and public authorities



Organ exchange organisations, national agencies and public authorities were more comfortable with the second option, although the support for the third option is also considerable.

- iii. There was, however, general agreement that the content of a possible future directive should be limited to establishing a basic quality and safety framework for Europe and, at the same time, it should respect clinical practice. Binding requirements should not create any barriers for organ donation, including the use of the so-called “expanded criteria donors” under specific circumstances. A comprehensive assessment of the impact should be presented with the proposal.
- iv. There is common agreement that organ shortage is the main problem in the field. The majority of responses recognised the added value of a Community action in this field; only four responses were against this general conclusion.

Developing national or regional systems to an optimum level of performance is a prerequisite for wider European cooperation. These systems need an appropriate legal framework, a good technical approach and adequate organizational support. Sharing the best practice and expertise, promoting the best of the best models were also among the suggestions received.

Most respondents did not consider a centralised European donor pool as a good option. However, they pointed out the added value of an active cooperation between Member States or existing organ exchange organisations. Some of the actions mentioned were: coordination of training of professionals; using benchmarks between Member States to identify areas of improvement and determining priorities; and coordination of programmes oriented to facilitate the identification of organs for urgent patients and highly sensibilised patients, in particular in small EU countries with a limited size of national donor pool. Other actions identified were the development of consensus guidelines and of professional standards to ensure good medical practice and the evaluation of post- transplant results (“organovigilance”), including monitoring adverse events that could lead to a safer and more effective use of organ donors.

Promotion of the donation was one of the most supported suggestions. Awareness-raising activities were suggested and the need to shape these activities into a society-oriented approach. The involvement of all stakeholders in the process (regulators, health care professionals, patients and donor associations, media, opinion and religious leaders, educational professionals, judges, etc.) was pointed out as a key factor for success.

Many contributors emphasised that the use of living donors should be promoted.

- v. Access to transplants was recognised as a problem not only between Member States but also within Member States, partially as a consequence of the shrinking donor rate.

Accessibility is a complex issue, like other healthcare access issues, and it cannot be separated from the general healthcare environment. Many respondents believed that better coordination between Member States would improve the situation, but it is not the only aspect to be addressed. Access to transplants requires, for example, financial and human resources that take time to be created.

- vi. Some contributions highlighted "transplant tourism", where potential recipients from one country are trying to get a transplant from or in another country. Another issue that was identified, but not addressed in this consultation document, is the growing number of non-EU citizens on a waiting list for organ transplantation in the EU border region. This increases the current shortage of organs and at the same time it confronts the EU with ethical dilemmas.

There was general support of exploring initiatives to combat organ trafficking.

4. CONCLUSION

The Commission will take into account the results of this open consultation to address the specific problems in the domain of organ donation and transplantation. The main problems encountered relate to quality and safety aspects of organ transplantation, shortage of organs and organ trafficking. These should be addressed in the context of Community competence in order to propose the best alternatives for EU action.

Report on the open consultation: Policy options for organ donation and transplantation at EU level

In June 2006, DG 'Health and Consumer Protection' launched an open consultation on organ donation and transplantation. Stakeholders were invited to express their position on the basis of a Consultation document on "Organ donation and transplantation: Policy options at EU level". The public consultation closed in September 2006.

The aim of the consultation was to identify the main problems encountered in organ donation and transplantation, to invite ideas on EU initiatives that could help to solve these problems, and to determine the extent to which measures should be taken at Community level.

In the consultation, three possible scenarios were outlined for future EU action with regard to organ donation and transplantation.

This document summarises some key elements of the 73 contributions made by stakeholders. There was agreement that quality and safety of organs need to be ensured, and that at present the main problem is the shortage of organs.

The contributions to the consultation can be found in full at:

http://ec.europa.eu/health/ph_threats/human_substance/oc_organ/oc_organ_contributions_en.htm

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