



COMMISSION OF THE EUROPEAN COMMUNITIES

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**REPORT FROM THE COMMISSION TO THE COUNCIL
AND THE EUROPEAN PARLIAMENT**

**on the promotion by Member States of voluntary
unpaid donation of tissues and cells**

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1. INTRODUCTION

In accordance with Article 12 of Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells¹, this report summarises the measures taken by Member States² to endeavour to ensure voluntary unpaid donations and identifies the measures the Commission intends to take at Community level. The individual national reports can be consulted on the SANCO website: http://ec.europa.eu/health/ph_threats/human_substance/blood_tissues_organs_en.htm.

This report covers the donation of tissues and cells in general. The donation of reproductive cells more specifically has been the object of a separate report.³ The information received from the Member States on the measures taken to endeavour to ensure voluntary unpaid donations of tissues and cells has been complemented where appropriate with the findings of the report on reproductive cells.

2. THE PRINCIPLE OF VOLUNTARY UNPAID DONATION

The principle of voluntary unpaid donation of tissues and cells was recognised for the first time in Spain in 1979 and in Luxembourg, Belgium and Finland in the early 1980s. Although the principle of voluntary unpaid donation for blood has been an accepted practice for over 50 years in many Member States⁴, most Member States have recognised the principle for tissues and cells only since the 1990s or since 2000.

Since 2006, the principle has been legally recognised by all 24 reporting Member States. The two Member States (Cyprus and Malta) that had no regulation governing the principle of voluntary unpaid donation of tissues and cells introduced it in their legislation when transposing the Tissues and Cells Directive. The UK and Ireland have now introduced the principle in legislation where it used to be in guidelines before (see Figures 1 and 2⁵).

No Member State is aware of cases where donors have been remunerated for the donation of tissues and cells.

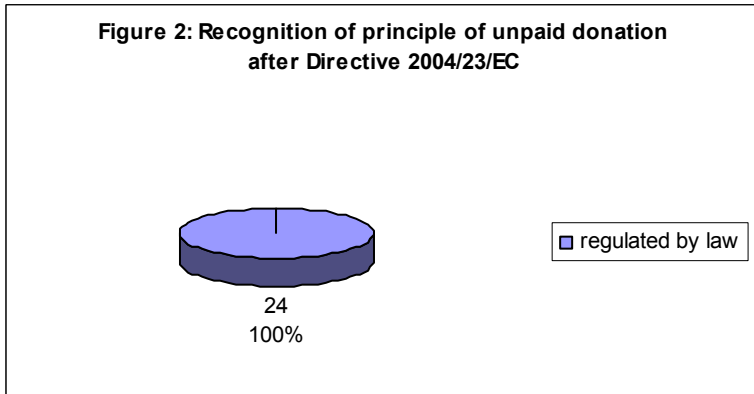
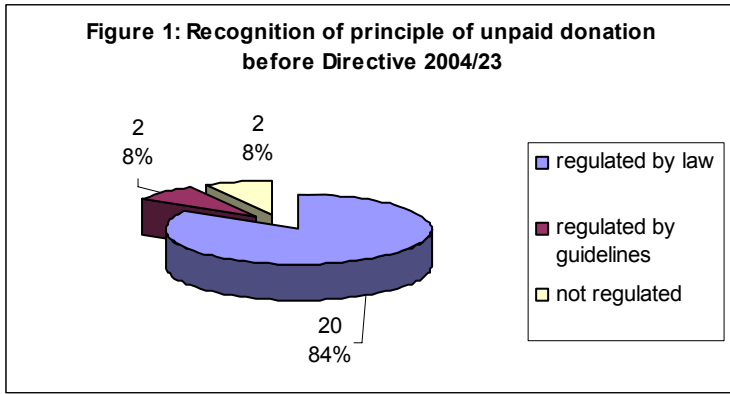
¹ OJ L 102, 7.4.2004, p. 48.

² Twenty-four Member States have sent in a national report, Greece has not done so yet.

³ Report on the Regulation of Reproductive Cell Donation in the European Union, http://ec.europa.eu/health/ph_threats/human_substance/tissues_en.htm.

⁴ Report on the voluntary and unpaid donation of blood, at: http://ec.europa.eu/health/ph_threats/human_substance/keydo_blood_en.htm.

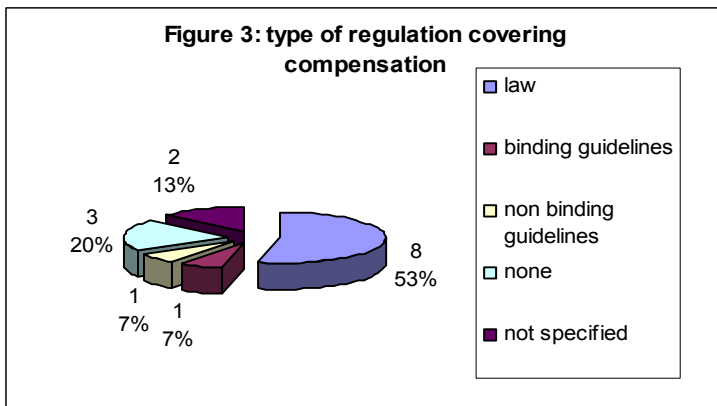
⁵ Figures 1 and 2: 100% refers to the 24 Member States that have sent in a report.



3. COMPENSATION FOR THE DONATION OF TISSUES AND CELLS

Under the principle of voluntary unpaid donation of tissues and cells, donors cannot be remunerated but may receive compensation strictly limited to making good the expenses and inconvenience related to the donation. The Member States define the conditions under which compensation may be granted.⁶

Fifteen Member States currently allow for donors to be compensated, but nine do not (Austria, Estonia⁷, Latvia, Lithuania, Malta, Poland, Portugal, Slovakia and the Netherlands). Of the countries allowing donors to be compensated, the majority have defined the conditions for granting compensation by law or government rules. Denmark, Ireland and Sweden state that they have not defined such conditions, see Figure 3.⁸



⁶ Article 12 of Directive 2004/23/EC.

⁷ Compensation can only be given for the donation of gametes.

⁸ Figure 3: 100% refers to the 15 Member States that allow for compensation.

Some countries only allow for compensation of the expenses or inconveniences related to the donation of certain types of tissues or cells. In Estonia, only gamete donors can be compensated for their expenses. The UK only allows compensation in some limited live donor situations, such as the donation of bone marrow.

The type of expenses compensated differs amongst Member States. Member States sometimes specify that only those expenses that are not reimbursed by social insurance can be compensated (Hungary). Several Member States indicate that expenses can be reimbursed only if documented and only at actual cost (Cyprus, Denmark, Hungary, Italy).

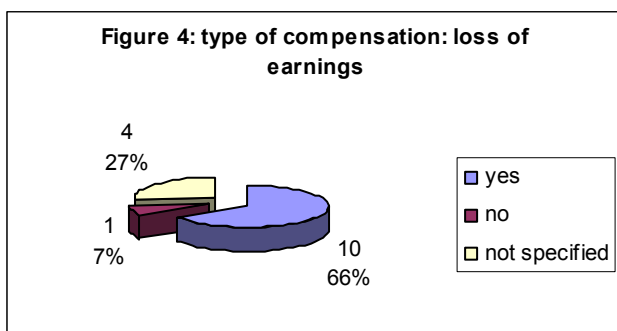
3.1. Travel expenses

All 15 Member States that allow compensation reimburse travel expenses.

The Czech Republic only reimburses travel expenses for public transportation, Finland allows for reimbursement of travel costs when they are related to treatment for illness or rehabilitation. In the UK, compensation for the donation of haematopoietic stem cells also covers the travel expenses of one family member or friend accompanying the donor. France has a similar system for reimbursing the accommodation costs of an accompanying person.

3.2. Loss of earnings

The second type of compensation commonly allowed is compensation for loss of earnings (see Figure 4)⁹. The conditions under which such compensation is paid differ. In the Czech Republic, lost pay is reimbursed up to a maximum of 92 hours. In Finland, the donor of an organ or tissue who loses income for at least an entire day because of the removal of an organ or tissue to meet a vital transplantation need¹⁰ and does not otherwise receive compensation for this period is entitled to a daily allowance. Spain only provides compensation for loss of earnings in the case of self-employed persons who do not have a basic salary.



3.3. Time off work

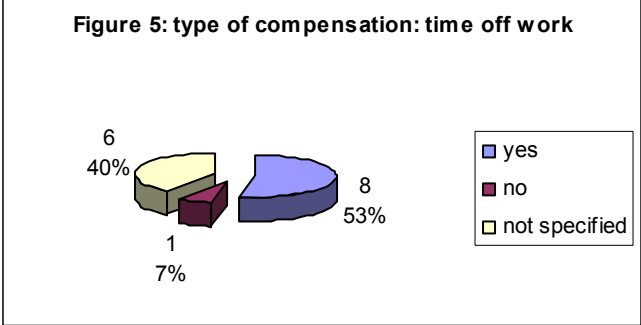
Time off work is given in about half of the Member States that allow for compensation (see Figure 5)¹¹. However, this result should be read together with the findings regarding compensation for loss of earnings. In most cases, one or the other is provided.¹²

⁹ Figure 4: 100% refers to the 15 Member States that allow for compensation. Belgium, Cyprus, the Czech Republic, Finland, France, Hungary, Luxemburg, Spain and the UK provide compensation for loss of earnings, Italy does not.

¹⁰ Or for essential related tests and examinations.

¹¹ Figure 5: 100% refers to the 15 Member States that allow for compensation. Denmark, Finland, France, Germany, Italy, Slovenia, Spain and Sweden give time off work, Hungary does not.

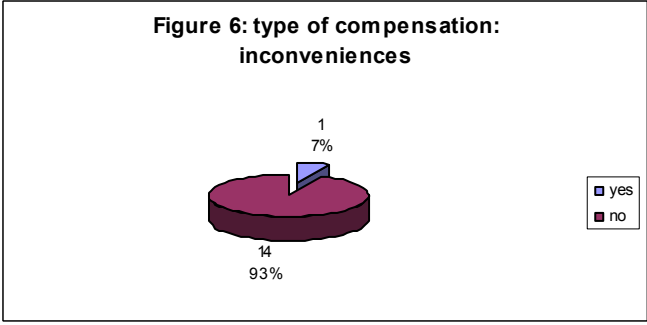
Whether time off work is given depends on the case and the medical opinion of the physician (Finland, Germany, Slovenia and Spain). France provides time off work for donors during their hospitalisation, which is two to six weeks for kidney donation and a few days for haematopoietic stem cell donation. Giving time off work would be considered acceptable in Denmark, but the situation rarely arises, because many donors are in-house patients, deceased donors or students.



3.4. Compensation for inconvenience

Only one Member State, Denmark, indicates that compensation for discomfort endured during the donation of tissues and cells would be considered acceptable (see Figure 6¹³). However, the Danish National Board of Health is not aware that this practice is generally employed, except for reproductive cells. From the information received for the report on the donation of reproductive cells, it appears that the Czech Republic also takes into account the discomfort endured when donating reproductive cells.

Sweden argues that no compensation should be given for discomfort or inconvenience, as this would come close to paying donors.



3.5. Other types of compensation

Several Member States indicate that the medical costs of donation are covered by social security (Austria, Belgium, France, and Poland).

¹² Only Ireland did not give information in this regard.
¹³ Figure 6: 100% refers to the 15 Member States that allow for compensation.

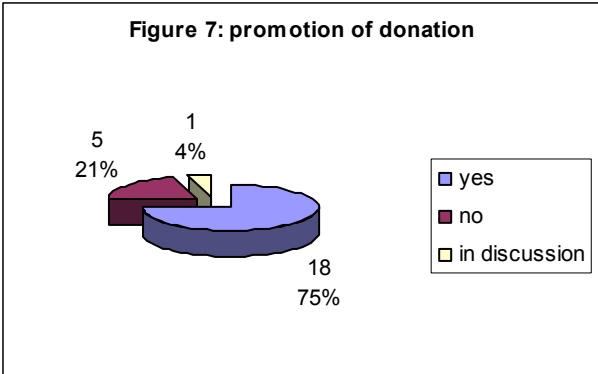
Other types of compensation include accommodation (Cyprus, France, Hungary, Ireland and Spain), refreshments (the Czech Republic, Denmark, Ireland, Sweden and the UK), a formal letter given to cell donors or their employers (Czech Republic), compensation for a medical accident connected with donation in France, or acknowledgements such as titles. Polish donors of bone marrow or other regenerating tissues or cells are for example awarded the title of “Graft Donor” or “Meritorious Graft Donor” if they have donated more than once, together with a membership card and a special badge. These donors also enjoy the privilege of using outpatient public health care services without appointment.

4. PROMOTION OF VOLUNTARY UNPAID DONATION OF TISSUES AND CELLS

4.1. Promotion of the donation of tissues and cells

Most Member States undertake activities to promote the donation of tissues and cells (see Figure 7)¹⁴. The measures range from information campaigns, making use of advertisements, conferences, posters, TV/radio spots, info telephones and websites, to the production of booklets, the funding of registers of volunteers or the organisation of student awareness programmes or donor days. Authorities also organise training for transplant coordinators and collaborate with patients’ associations on awareness raising. They use both the mass media for the broad distribution of messages and local initiatives to improve procurement. Some promotional measures are directed towards specific subpopulations such as ethnic groups¹⁵, students, judges or minority groups. The possibility to register online as a donor is also used as a means to encourage donation.

In the Czech Republic, Hungary and Portugal, promotional measures seem to focus on bone marrow donation, while in other countries (Lithuania, Sweden, UK) the promotion of donation is generally linked to organ donation, not so much to tissues and cells. The UK has also organised a specific campaign to promote the donation of gametes to prepare for the removal of anonymity.



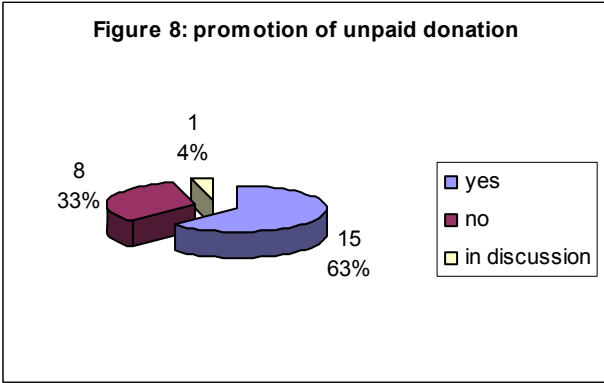
¹⁴ Figure 7: 100% refers to the 24 Member States that sent in a report. Estonia, Ireland, Latvia, Luxemburg and Slovakia have not taken measures to promote donation. The promotion of donation is under discussion in Austria.

¹⁵ To improve the availability of various HLA types, it is important to target ethnic groups because they have different HLA types.

4.2. Promotion of the unpaid character of donation

Most Member States undertake activities to promote the donation of tissues and cells, but not all organise activities in order to advertise specifically the unpaid character of the donation (see Figure 8).¹⁶ One reason advanced for this is the fact that the unpaid character of the donation is fixed by law (Finland). The UK on the other hand sees the legislation as an added advantage in its campaigns to make it perfectly clear that donation should be unpaid.

The unpaid character of donation is promoted by means similar to those mentioned for the promotion of donation as such.



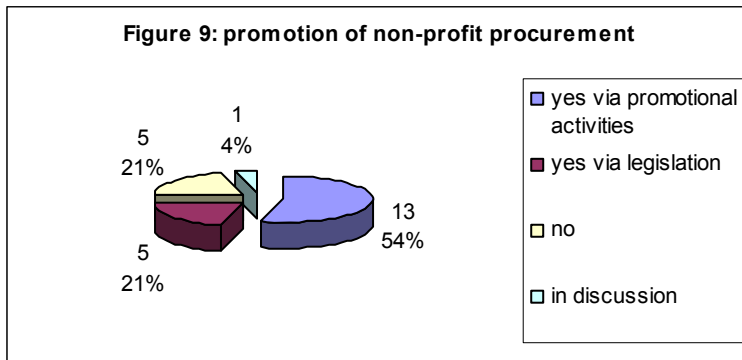
4.3. Promotion of the non-profit procurement of tissues and cells

Most Member States also take measures to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis (see Figure 9¹⁷). Denmark, Italy, Latvia, Lithuania and Slovakia mention only their legislation prohibiting for profit procurement as measures they have taken. In contrast, Belgium, Cyprus, the Czech Republic, Finland, France, Germany, Hungary, Poland, Portugal, Slovenia, Spain, Sweden and the UK implement a broader range of measures. Some Member States focus on the annual financial reporting of procurement organisations to the authorities and on financial (Belgium) or general (France) inspections, while in other Member States the fact that procurement is carried out by institutions that are part of the national health system or by institutions receiving public funding ensures that the procurement of tissues and cells is on a non-profit basis (Czech Republic, Hungary, Poland, Portugal, Sweden).

Estonia, Ireland, Luxemburg, Malta and the Netherlands have not taken measures to endeavour to ensure that the procurement of tissues and cells is carried out on a non-profit basis.

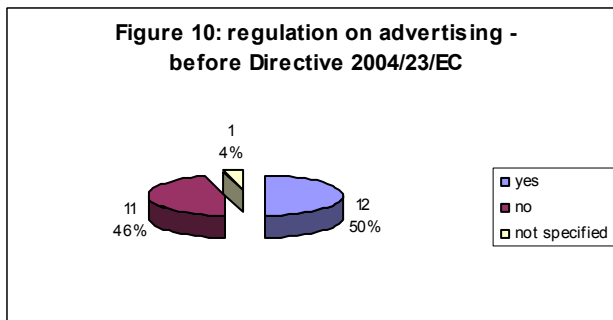
¹⁶ Figure 8: 100% refers to the 24 Member States that sent in a report. Denmark, Finland and Malta have taken measures to promote donation, but not specifically to promote unpaid donation.

¹⁷ Figure 9: 100% refers to the 24 Member States that sent in a report.

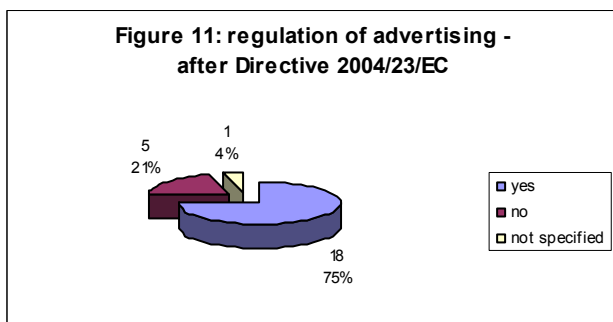


5. ADVERTISING

Before the transposition of the Tissues and Cells Directive, half of the Member States (see Figure 10¹⁸) had regulation in place restricting or prohibiting the advertising of the need for or availability of human tissues and cells with a view to offering or seeking financial gain or comparable advantages.



Austria, Cyprus, Ireland, Malta, Slovakia and the UK have introduced or will introduce such regulation upon transposing the Tissues and Cells Directive (see Figure 11¹⁹). Denmark, Finland, Latvia and Portugal have no such regulation yet.



Denmark states that although it has no specific legislation imposing restrictions or prohibitions on advertising in relation to tissues and cells, its law on the marketing of health services prohibits the marketing of health services on TV, film, video or the like. Also, the general regulation prohibiting for profit procurement would most likely apply.²⁰ Estonia only

¹⁸ Figure 10: 100% refers to the 24 Member States that sent in a report.

¹⁹ Figure 11: 100% refers to the 24 Member States that sent in a report.

²⁰ The Danish Health Act, § 268(2).

has specific legislation concerning advertising for artificial insemination, while for other activities the general legislation on the advertising of health services applies. Luxemburg²¹ and Lithuania²² refer to the general principle of free donation and the prohibition of commercial transactions relating to tissues and cells enacted in their legislation.

The prohibitions can be broad or more specific. They range from prohibiting any advertising relating to organs, tissues and cells, except for the general promotion of donation, to prohibiting advertising in favour of a specific person or institution or advertising with a view to offering or seeking financial gain or comparable advantage.

6. CONCLUSIONS

Although the principle of voluntary unpaid donation is recognised by the Member States, the concrete interpretation of this principle differs across Member States. Most Member States (62.5%) allow compensation to be offered to donors of tissues and cells. Of these countries, most allow only for the compensation of expenses. Even though the Tissues and Cells Directive allows for compensation to be given for inconvenience, only one Member State states, for the donation of tissues and cells in general,²³ that this would also be considered acceptable. The question seems to be whether giving compensation for the inconvenience associated with the donation should be considered as an incentive or not. It is also more difficult to quantify compensation for inconvenience objectively than for expenses incurred.

Several Member States mention the need to justify the expenses for which compensation is sought. Expenses should be documented, which implies that no flat-rate reimbursement should be offered.

Very little information is given on the actual amounts reimbursed²⁴, because the amount of the compensation paid will depend on the individual circumstances of the donor: number of times the donor has to visit the hospital, length of the stay at the hospital, distance from the donor's home to the hospital, treatments to be undergone, effects of the donation on capacity to work etc. Practices may also vary according to the clinic concerned.

Different initiatives exist to promote the principle of voluntary unpaid donations, using techniques as diverse as advertising, student information programmes and donor days. The measures taken do not always cover both the donation as such and the unpaid character of the donation. More attention is given to the need to increase donation of tissues and cells than to the promotion of the non-profit character of the donation.

Not all Member States have regulation imposing restrictions or prohibitions on advertising of tissues and cells with a view to offering or seeking financial gain or comparable advantages. The restrictions or prohibitions that are in place also vary in scope.

²¹ Loi du 25 novembre 1982 réglant le prélèvement de substances d'origine humaine.

²² Law of 25 March 2004 on the Amendment on Human Tissues, Cells and Organ Donation and Transplantation.

²³ Two Member States allow compensation for inconvenience when reproductive cells are donated.

²⁴ For the donation of reproductive cells, some Member States have maximum limits for reimbursement (Spain, UK) while others indicate the range within which compensation can be paid. Report on the Regulation of Reproductive Cell Donation in the European Union, http://ec.europa.eu/health/ph_threats/human_substance/tissues_en.htm.

7. ACTION PLAN

The Commission suggests the following actions:

1. Member States should collect more detailed information on the day-to-day practice of compensation at different hospitals or procurement organisations, which they can then communicate to the Commission.
2. On the basis of the information collected, the Commission will investigate with Member States the need for issuing guidelines to implement the principle of unpaid donation. Such guidelines could concern, for Member States allowing compensation, the need for transparency regarding the type of compensation offered and regarding the composition of the amount paid, or the need to document the expenses to be reimbursed.
3. On the basis of the information collected, the Commission will investigate with Member States the need for issuing guidelines for interpreting the requirement of Article 12(2) of the Tissues and Cells Directive to have appropriate restrictions or prohibitions on advertising the need for or availability of human tissues and cells with a view to offering or seeking financial gain or comparable advantages.