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**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE
COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE
COMMITTEE OF THE REGIONS**

2nd Report on Voluntary and Unpaid Donation of Tissues and Cells

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1. INTRODUCTION

The principles governing tissue and cell donation are set out in article 12 of Directive 2004/23/EC¹. It states that *Member States shall endeavour to ensure voluntary and unpaid donations of tissues and cells. Donors may receive compensation, which is strictly limited to making good the expenses and inconveniences related to the donation. In that case, Member States define the conditions under which compensation may be granted.*

In addition, Member States shall take all necessary measures to ensure that any promotion and publicity activities in support of the donation of human tissues and cells comply with guidelines or legislative provisions laid down by the Member States. Such guidelines or legislative provisions shall include 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 advantage.

Member States shall endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis.

Donated tissues and cells, such as skin, bones, tendons, corneas and haematopoietic stem cells, are increasingly used in medical therapies and as starting material for advanced therapy medicinal products (ATMP). In addition, reproductive cells² are used in the field of medically assisted reproductive technology (ART), e.g. in vitro fertilization (IVF) and other so-called ART techniques to achieve pregnancy by artificial or partially artificial means.

In accordance with Article 12-1 of Directive 2004/23/EC, Member States shall submit reports on the practice of voluntary and unpaid donation to the Commission every three years. The first Commission report on the promotion by Member States of voluntary unpaid donation of tissues and cells was published in 2006³.

This Commission report is based on the Member States' responses to a report template on voluntary and unpaid donation of tissues and cells, which was sent to the Competent Authorities for tissues and cells during the summer of 2010. All Member States submitted a report to the Commission. In addition, Liechtenstein and Norway submitted a report (in total 29 reporting countries). The main findings of this report have been presented to the Competent Authorities for tissues and cells⁴.

This report aims to provide an overview of the practice of voluntary and unpaid donation of tissues and cells, focusing on (1) legislative provisions, guidelines and

¹ Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

² Directive 2006/17/EC defines reproductive cells as "all tissues and cells intended to be used for the purpose of assisted reproduction".

³ COM/2006/0593 final.

⁴ http://ec.europa.eu/health/blood_tissues_organ/docs/ev_20101206_mi_en.pdf

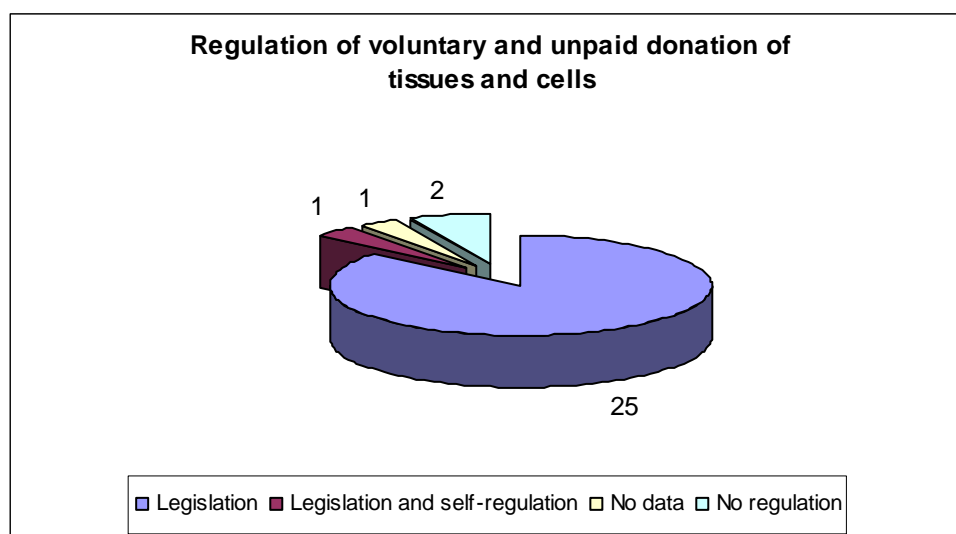
policies, (2) compensation and incentives, (3) promotion and advertising, and (4) procurement and supply.

2. RESULTS

2.1. Legislative provisions, guidelines and policies

27 of the 29 reporting countries have some form of provisions governing the principle of voluntary and unpaid donation of tissues and cells (binding or non-binding).

Figure I



As shown in figure I, 25 countries have binding rules concerning voluntary and unpaid donation of tissues and cells in their national regulations (Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, the United Kingdom and Norway). Malta has a dual system with binding rules laid down by national regulation and rules set by the sector (self-regulatory), while Ireland and Liechtenstein have no legislative provisions governing this field. No data was reported from Austria on this point.

These legislative provisions or guidelines have been subject to change in a number of countries. Since 2006, when the first report on the promotion by Member States of voluntary and unpaid donations of tissues and cells was issued by the Commission, Bulgaria, Czech Republic, Poland, Portugal and the United Kingdom have updated or changed their provisions on voluntary and unpaid donation of tissues and cells. In addition, Bulgaria, Ireland, Malta and Liechtenstein state that they are planning to update or change their legislative provisions or guidelines in the field.

Penalties for infringements of the legislative provisions on voluntary and unpaid donation of tissues and cells have been defined in 23 countries (Austria, Bulgaria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany,

Greece, Hungary, Italy, Lithuania, Luxembourg, the Netherlands, Poland, Portugal, Romania, Slovenia, Sweden, the United Kingdom and Norway). 1 country has imposed such penalties (Czech Republic).

2.2. Compensation and incentives

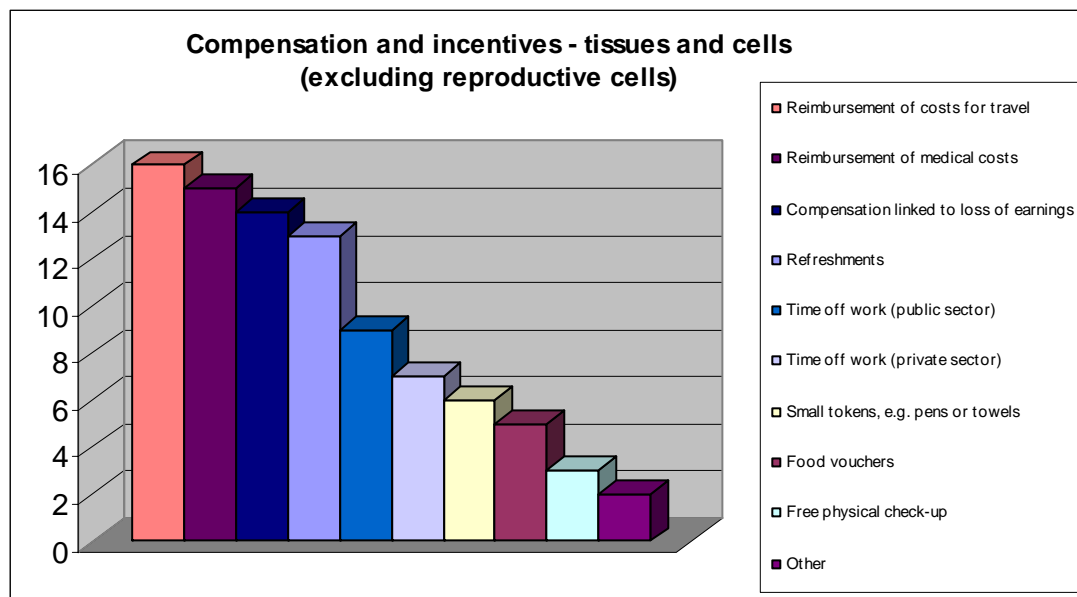
13 countries have guiding principles regarding the possibility of giving forms of compensation or incentives to donors of tissues and cells (Bulgaria, Czech Republic, Denmark, Finland, Hungary, Greece, Italy, Lithuania, Malta, the Netherlands, Slovenia, Spain and the United Kingdom).

19 countries report providing some form of compensation or incentives for living donors of tissues and cells (excluding reproductive cells), namely Belgium, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Slovakia, Slovenia, Spain, Sweden and the United Kingdom.

The following 14 countries give some form of compensation or incentives for the donation of reproductive cells: Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Hungary, the Netherlands, Portugal, Slovakia, Slovenia, Spain and Norway.

4 countries provide forms of compensation or incentives to relatives of deceased donors (Bulgaria, Romania, Slovenia, and Spain) (see figures II-IV).

Figure II



As shown by figure II, the main forms of compensation and incentives given to donors of tissues and cells (excluding reproductive cells) are reimbursement of costs of travel, reimbursement of medical costs, compensation linked to loss of earnings and refreshments.

Figure III

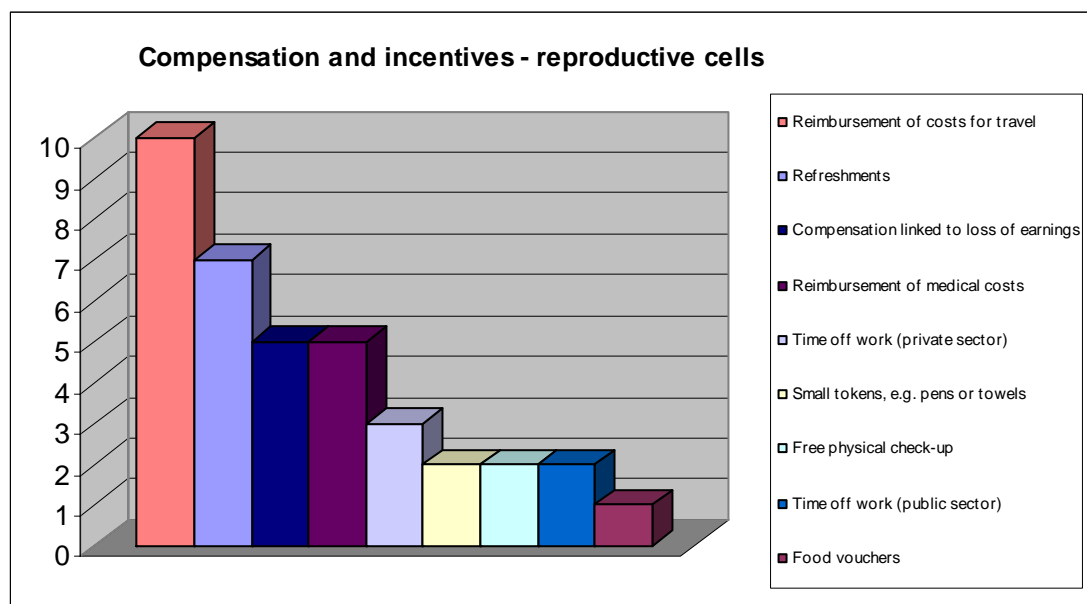


Figure III demonstrates major forms of compensation and incentives given to donors of reproductive cells, including reimbursement of travel costs and refreshments.

Figure IV

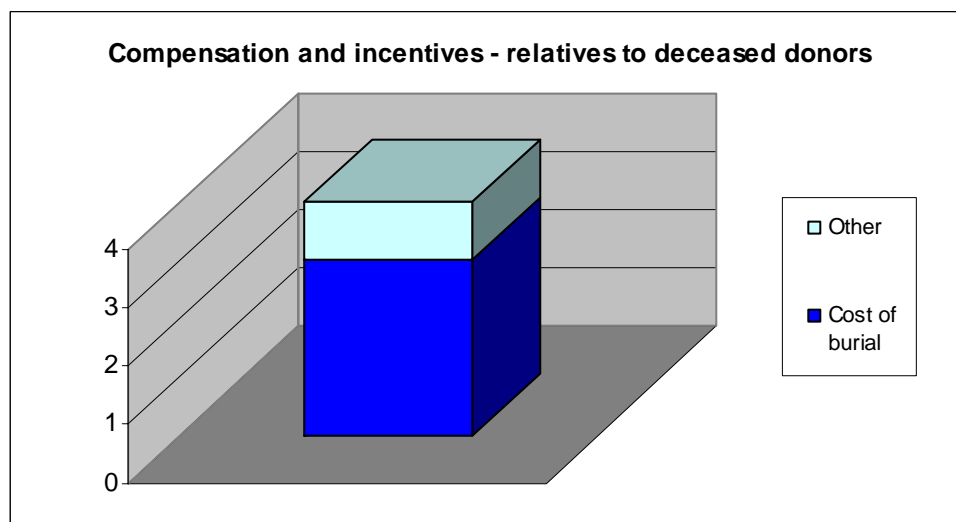
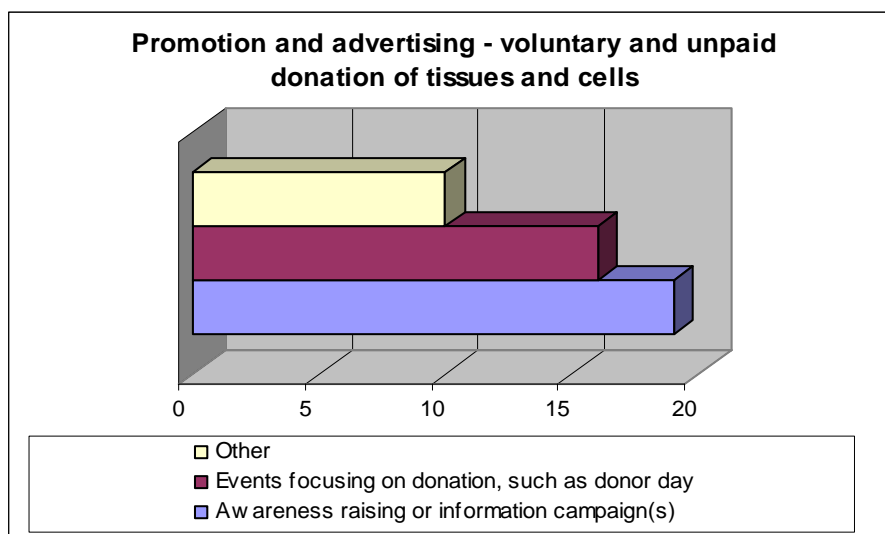


Figure IV illustrates the main forms of compensation and incentives given to relatives of deceased donors.

2.3. Promotion and advertising

The following countries report having taken measures to promote voluntary and unpaid donation of tissues and cells: Belgium, Bulgaria, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Lithuania, Malta, the Netherlands, Poland, Portugal, Slovenia, Spain, Sweden and the United Kingdom.

Figure V



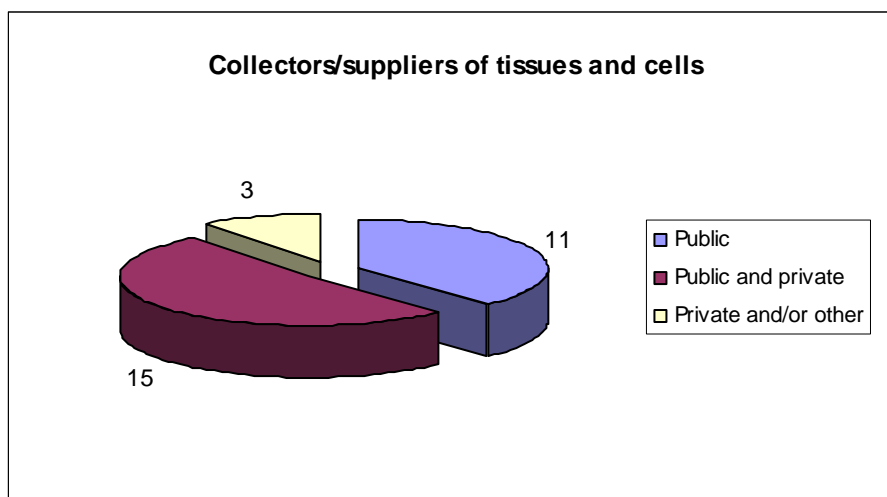
As demonstrated by the figure above, the most commonly used measures to promote voluntary and unpaid donation of tissues and cells are events focusing on donation, awareness raising and information campaigns. 11 countries have specific target groups for promotion and advertisements, such as students, medical professionals, hospital employees, the police and army forces, blood donors and certain minorities (for cord blood banks).

As set out in article 12-2 of Directive 2004/23/EC, Member States shall take all necessary measures to ensure that any promotion and publicity activities in support of the donation of human tissues and cells comply with guidelines or legislative provisions laid down by the Member States. Such guidelines or legislative provisions shall include 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 advantage. The following 23 countries report having such restrictions on advertisements: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Italy, Lithuania, Luxembourg, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom. Penalties for infringements of these restrictions have been defined in 20 countries.

2.4. Procurement and supply

The majority of the reporting countries have public collectors/suppliers of tissues and cells (Belgium, Hungary, Italy, Lithuania, the Netherlands, Poland, Portugal, Slovakia, Spain, Sweden and Norway) or a dual system of private and public collectors/suppliers (Austria, Bulgaria, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Ireland, Luxembourg, Malta, Romania, Slovenia and the United Kingdom). The remaining three countries have private and/or other collectors/suppliers of tissues and cells (Cyprus, Latvia and Liechtenstein) (see figure VI).

Figure VI

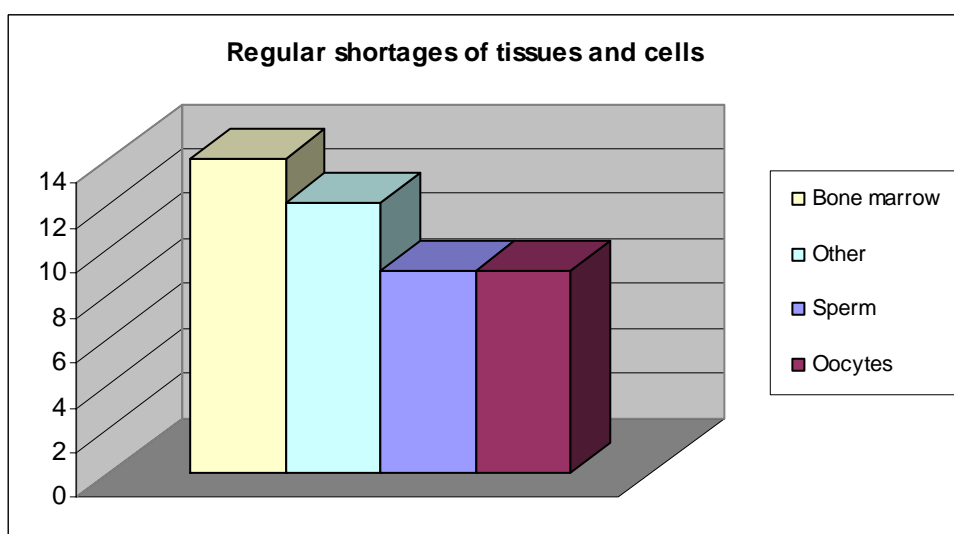


Around 30% of the reporting countries provide some form of financial incentives for the procurement of tissues and cells, e.g. to hospitals, health care personnel or tissue establishments.

Regarding self-sufficiency, 11 countries have policies in place to endeavour to promote self-sufficiency of tissues and cells (Bulgaria, Czech Republic, France, Italy, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Sweden and Norway). In addition, 17 countries have bilateral or other forms of agreements/collaboration structures to ensure national supply of tissues and cells (Belgium, Bulgaria, Czech Republic, Denmark, Estonia, Greece, Ireland, Italy, Lithuania, Luxembourg, Malta, Portugal, Slovakia, Slovenia, Spain, Sweden and Liechtenstein).

Finally, in relation to supply, several countries report regular shortages of tissues and cells on a national level (see figure VII).

Figure VII



As demonstrated in the figure above, almost half of the reporting countries experience regular shortages of bone marrow, and nine countries report regular shortages of sperm and oocytes. Other tissues and cells subject to shortages include corneas, bones, tendons and skin.

3. SUMMARY AND CONCLUDING REMARKS

This report shows that Member States overall comply with Article 12 of Directive 2004/23/EC, requiring Member States to take the necessary measures to endeavour to ensure voluntary and unpaid donations of tissues and cells.

Largely in line with the findings of the first report on voluntary and unpaid donation of tissues and cells (issued 2006), this report shows that legislative provisions and guidelines on voluntary and unpaid donation of tissues and cells are well established across the EU. 27 out of the 29 reporting countries have such legislative provisions or guidelines in place.

19 of the reporting countries have some form of compensation or incentive structures for donors of tissues and cells (excluding reproductive cells), such as reimbursement of travel and medical costs. For reproductive cells, about half of the countries provide some forms of compensation or incentives, including reimbursement of travel costs, refreshments and compensation linked to loss of earnings. In addition, four countries give some form of compensation or incentives to relatives of deceased donors.

19 countries have undertaken some form of measures to promote voluntary and unpaid donation of tissues and cells, such as awareness raising and information campaigns. In addition, 23 countries have 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 advantage (in line with article 12 of Directive 2004/23/EC).

Concerning the procurement and supply of tissues and cells, this report shows that the majority of the countries have public collectors/suppliers or a dual system of public and private collectors/suppliers. With regards to supply, 11 countries report having policies in place to endeavour to promote self-sufficiency of tissues and cells, and 17 countries have bilateral or other forms of agreements/collaboration structures to ensure national supply of tissues and cells. However, almost half of the countries report some form of shortages of tissues and cells, including bone marrow and gametes.

As set out in Article 12 of Directive 2004/23/EC, the Commission shall inform the European Parliament and the Council of any necessary further measures it intends to take in the field of voluntary and unpaid donation of tissues and cells. Based on the findings of this report, the Commission will now, together with the Member States, reflect on the potential need for further measures, keeping in mind that the Commission's legal mandate is limited to quality and safety of tissues and cells.