



**Survey on measures taken by Member States to endeavour to ensure  
voluntary and unpaid donations of tissues and cells in compliance with  
article 12 of Directive 2004/23/EC**

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This is the first report requested from Member States on measures to ensure voluntary and unpaid donations of tissues and cells. We would therefore like to compare the situation as it was before the implementation of Directive 2004/23 with the situation as it is or will be after the implementation.

If the implementing measures of the Directive are not in force yet, please refer to the draft version of that implementing regulation and indicate the timeframe for adoption of that regulation.

This report does not address reproductive cells specifically, since they have been the object of a separate survey on reproductive medicine. The results of this survey are published in the Report on legislation on the donation of reproductive cells in the EU ([http://ec.europa.eu/health/ph\\_threats/human\\_substance/tissues\\_en.htm](http://ec.europa.eu/health/ph_threats/human_substance/tissues_en.htm)).

## Explanation of the initials used in the survey

Explanation of the initials used in the questionnaire:

- L: It is explicitly included in the Law or government rules and it is binding.
- G: It is included in national organisations Guidelines and it is binding.
- GNO: It is recommended by national organisations Guidelines but it is not binding.
- N: Not regulated at all

# AUSTRIA

## I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>              |
|--|--|---|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | <input checked="" type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N  | <input checked="" type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  | Bundesgesetzblatt über Krankenanstalten und Kuranstalten (Federal Law on Hospitals) BGBl. I Nr. 55/2005<br>Allgemeines Bürgerliches Gesetzbuch (General Civil Code) vom 1. Juni 1881 JGS 946, zuletzt geändert durch BGBl I Nr. 120/2005 | Gewebesicherheitsgesetz (Federal Law on Tissue Safety)  |
| <b>3. Date of the regulation</b><br>(dd/mm/yyyy)   | Before 1995  | 2007  |
| <b>4. Entry into force of the regulation</b><br>(dd/mm/yyyy)   | Before 1995  | 2007  |

## II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|   | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>                        | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>           |
|---|--|--|
| <b>1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?</b>   | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>  | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>  |
| <b>2. Where are the conditions defined under which compensation may be granted</b>  | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input checked="" type="checkbox"/> | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/><br>In discussion |
| <i>If this regulation is different from the one mentioned under question 1, please indicate its title, date and date of entry into force</i>  |  |  |
| <b>3. What does this compensation entail?</b> (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |  |  |

|   |   |           |
|---|---|-----------|
| a. Expense allowance<br>(please specify the type of expenses covered)   | <i>na</i>   | <i>na</i> |
| b. Time off work<br>(please indicate duration)  | <i>na</i>   | <i>na</i> |
| c. Compensation for discomfort endured<br>(please specify)  | <i>na</i>   | <i>na</i> |
| d. Refreshments<br>(please specify)   | <i>na</i>   | <i>na</i> |
| e. Others (please specify)  | <i>na</i>   | <i>na</i> |
| f. If there are specific rules for certain types of tissues/cells, please specify   | <i>na</i>   | <i>na</i> |
| <b>4. Are you aware of cases in your country where donors were given <u>remuneration</u> for the donation of tissues and cells?</b> | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/><br><br>If you answered yes, please specify: |           |

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>         |
|---|--|---|
| <b>1. Have measures been taken to <u>promote donation</u> of tissues and cells</b><br>(please tick the appropriate box)                 | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>    | YES <input type="checkbox"/> NO <input type="checkbox"/><br><br>In discussion |
| <b>2. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, donor days, ...) |  |   |
| <b>3. Have measures been taken to <u>endeavour to ensure unpaid donation</u>?</b>   | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>    | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>           |
| <b>4. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, ...)             |  |   |

#### IV. Promotion of the non-profit procurement of tissues and cells

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|  | <b>Situation before the implementation of Directive 2004/23</b>     | <b>Situation after the implementation of Directive 2004/23</b>      |
|--|---|---|
| <b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br>(please tick the appropriate box) | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> |
| <b>2. Please describe the type of measures taken and the parties involved in their implementation</b>  |   |   |

#### V. Advertising

|   | <b>Situation before the implementation of Directive 2004/23</b>                    | <b>Situation after the implementation of Directive 2004/23</b>                                |
|---|--|---|
| <b>Do you have regulation providing for 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?</b><br>(please tick the appropriate box) | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>                | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>                           |
| <b>Type of regulation</b> (please tick the appropriate box)   | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> | L <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> |
| <i>If this regulation is different from the one mentioned under question 1, please indicate the title, date and date of entry into force of the regulation</i>  |  |   |
| <b>Describe the prohibitions</b>  |  | In discussion   |
| <b>Describe the restrictions</b>  |  | In discussion   |

## VI. Additional comments

If you have any additional comments or information please fill out the box below:

Ad II. Compensation for the donation of tissues and cells

The costs of medical procedure and the medical treatment of the donor are covered by social security and health insurance.

# BELGIUM

## I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>                        | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>  |
|--|--|---|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | X <input type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N | X <input type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N  |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  | Loi du 13 juin 1986 sur le prélèvement et la transplantation d'organes<br>law on donation and transplantation of organs  | Nouvelle loi relative à l'obtention et à l'utilisation de matériel coroprel humain destiné à des applications humaines ou à des fins de recherche scientifiques.<br>new law on tissues, cells and other materials from human origin |
| <b>3. Date of the regulation</b><br>(dd/mm/yyyy)   | 13/06/1986   | ?? still in discussion  |
| <b>4. Entry into force of the regulation</b><br>(dd/mm/yyyy)   | 24/02/1987   | ??  |

## II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|   | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>               | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b> |
|---|---|--|
| <b>1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?</b>   | YES <input type="checkbox"/> NO X <input type="checkbox"/>  | YES <input type="checkbox"/> NO X <input type="checkbox"/>   |
| <b>2. Where are the conditions defined under which compensation may be granted</b>  | L X <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/> | L X <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/>      |
| <i>If this regulation is different from the one mentioned under question 1, please indicate its title, date and date of entry into force</i>  |   |  |
| <b>3. What does this compensation entail?</b> (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |   |  |

|   |   |  |
|---|---|--|
| a. Expense allowance<br>(please specify the type of expenses covered)   |   |  |
| b. Time off work<br>(please indicate duration)  |   |  |
| c. Compensation for discomfort endured<br>(please specify)  |   |  |
| d. Refreshments<br>(please specify)   |   |  |
| e. Others (please specify)  |   |  |
| f. If there are specific rules for certain types of tissues/cells, please specify   |   |  |
| <b>4. Are you aware of cases in your country where donors were given <u>remuneration</u> for the donation of tissues and cells?</b> | YES <input type="checkbox"/> NO X <input checked="" type="checkbox"/><br><br>If you answered yes, please specify: |  |

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>   | <b>Situation <u>after</u> the implementation of Directive 2004/23</b> |
|---|--|---|
| <b>1. Have measures been taken to <u>promote donation</u> of tissues and cells</b><br>(please tick the appropriate box)                 | YES X <input checked="" type="checkbox"/> NO <input type="checkbox"/>  | YES X <input checked="" type="checkbox"/> NO <input type="checkbox"/> |
| <b>2. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, donor days, ...) | Campaign to promote organs, tissues and cells donation (conferences, posters, targeted people, radio spots, ...) | Same, continuing  |
| <b>3. Have measures been taken to <u>endeavour to ensure unpaid donation</u>?</b>   | YES X <input checked="" type="checkbox"/> NO <input type="checkbox"/>  | YES X <input checked="" type="checkbox"/> NO <input type="checkbox"/> |
| <b>4. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, ...)             | Regulation by law  | Regulation by law   |

#### IV. Promotion of the non-profit procurement of tissues and cells

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|  | <b>Situation before the implementation of Directive 2004/23</b> | <b>Situation after the implementation of Directive 2004/23</b> |
|--|---|--|
| <b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br>(please tick the appropriate box) | YES X <input type="checkbox"/> NO <input type="checkbox"/>      | YES X <input type="checkbox"/> NO <input type="checkbox"/>     |
| <b>2. Please describe the type of measures taken and the parties involved in their implementation</b>  | Annual financial reporting to authority + financial inspection  | Annual financial reporting to authority + financial inspection |

#### V. Advertising

|   | <b>Situation before the implementation of Directive 2004/23</b>  | <b>Situation after the implementation of Directive 2004/23</b>   |
|---|--|--|
| <b>Do you have regulation providing for 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?</b><br>(please tick the appropriate box) | YES X <input type="checkbox"/> NO <input type="checkbox"/>   | YES X <input type="checkbox"/> NO <input type="checkbox"/>   |
| <b>Type of regulation</b> (please tick the appropriate box)   | LX <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/>                        | L X <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/>                       |
| <i>If this regulation is different from the one mentioned under question I, please indicate the title, date and date of entry into force of the regulation</i>  |  |  |
| <b>Describe the prohibitions</b>  | Prohibition of any advertising related with organs, tissues and cells except general promotion of donation | Prohibition of any advertising related with organs, tissues and cells except general promotion of donation |
| <b>Describe the restrictions</b>  |  |  |

## VI. Additional comments

If you have any additional comments or information please fill out the box below:

Law ensure, at minimum, that donation and final delivery are made by an accredited tissue and cells bank. Processing and intermediate storage can be subcontracted to bio-engineering facilities. In this case, only the activities of the tissue and cells are true non-profit. The facilities accreditations are controlled by the pharmaceutical authority (GMP, ...), from the related country if necessary.

The delivery price is calculated, and imposed, by the authority in the scope of the national sickness insurance

# CYPRUS

## I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>                                   | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>   |
|--|---|--|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | <input type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input checked="" type="checkbox"/> N ✓ | <input type="checkbox"/> L* ✓<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N                                      |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  |   | The Quality and Safety Standards on Donation, Procurement, Testing, Processing, Preservation, Storage and Distribution of Human Tissues and Cells Law of 2006. |
| <b>3. Date of the regulation</b><br>(dd/mm/yyyy)   |   | -----  |
| <b>4. Entry into force of the regulation</b><br>(dd/mm/yyyy)   |   | Pending – Expected to be enforced on September 2006  |

\* Expected to be regulated through the implementation of the Quality and Safety Standards on Donation, Procurement, Testing, Processing, Preservation, Storage and Distribution of Human Tissues and Cells Law of 2006.

## II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|  | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>                             | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>          |
|--|---|---|
| <b>1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?</b>  | YES <input checked="" type="checkbox"/> ✓      NO <input type="checkbox"/>  | YES <input checked="" type="checkbox"/> ✓      NO <input type="checkbox"/>  |
| <b>2. Where are the conditions defined under which compensation may be granted</b>   | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input checked="" type="checkbox"/> ✓<br>N <input type="checkbox"/> | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input checked="" type="checkbox"/> ✓<br>N <input type="checkbox"/> |
| <i>If this regulation is different from the one mentioned under question I, please indicate its title, date and date of entry into force</i> |   |   |
| <b>3. What does this compensation entail?</b> (the level and type of compensation may differ)  |   |   |

|  |   |  |
|--|---|--|
| according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |   |  |
| a. Expense allowance<br>(please specify the type of expenses covered)  | -----   | -----  |
| b. Time off work<br>(please indicate duration)   | Where there is documented loss of income                            | Where there is documented loss of income                   |
| c. Compensation for discomfort endured<br>(please specify)   | -----   | -----  |
| d. Refreshments<br>(please specify)  | -----   | -----  |
| e. Others (please specify)   | Paid accommodation, food and transportation at actual cost          | Paid accommodation, food and transportation at actual cost |
| f. If there are specific rules for certain types of tissues/cells, please specify  | -----   | -----  |
| <b>4. Are you aware of cases in your country where donors were given remuneration for the donation of tissues and cells?</b>                   | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> |  |
|  | If you answered yes, please specify:                                |  |

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>  |
|---|---|--|
| <b>1. Have measures been taken to <u>promote donation of tissues and cells</u></b><br>(please tick the appropriate box)                 | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   | YES* <input checked="" type="checkbox"/> NO <input type="checkbox"/>   |
| <b>2. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, donor days, ...) | - Funding by the Ministry of Health for the creation of volunteer Bone Marrow Registry.<br>- Establishment of national Cord Blood Registry. | - Continuous funding by the Ministry of Health of the volunteer Bone Marrow Registry.<br>- Advertising material and campaigns. |
| <b>3. Have measures been taken to <u>endeavour to ensure unpaid donation?</u></b>   | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   | YES* <input checked="" type="checkbox"/> NO <input type="checkbox"/>   |

|   |   |  |
|---|---|--|
| <b>4. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, ...)<br> | - Ministry of Health officials participate in campaigns and other awareness raising events promoting the donation of tissues and cells. | - Awareness raising through participation of the Ministry of Health officials in campaigns and other events promoting the donation of tissues and cells<br>- Advertising material and campaigns. |
|---|---|--|

**IV. Promotion of the non-profit procurement of tissues and cells**

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|  | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>                     |
|--|---|---|
| <b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br>(please tick the appropriate box) | YES <input type="checkbox"/> ✓                      NO <input type="checkbox"/>   | YES* <input type="checkbox"/> ✓                      NO <input type="checkbox"/>          |
| <b>2. Please describe the type of measures taken and the parties involved in their implementation</b>  | - Establishment of Bone Marrow Registry in collaboration with non-governmental organisations in a non-profitable basis.<br>- Establishment of a public Bone Marrow Registry in collaboration with non-governmental organisations in a non-profitable basis. | - Drafting of Legislation regulating the non-profitable procurement of tissues and cells. |

\* Expected to be regulated through the implementation of the Quality and Safety Standards on Donation, Procurement, Testing, Processing, Preservation, Storage and Distribution of Human Tissues and Cells Law of 2006.

## V. Advertising

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>             | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>   |
|---|--|---|
| <b>Do you have regulation providing for 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?</b><br>(please tick the appropriate box) | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>                | YES* <input checked="" type="checkbox"/> NO <input type="checkbox"/>  |
| <b>Type of regulation</b> (please tick the appropriate box)   | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> | L* <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/>  |
| <i>If this regulation is different from the one mentioned under question I, please indicate the title, date and date of entry into force of the regulation</i>  |  |   |
| <b>Describe the prohibitions</b>  |  | <ul style="list-style-type: none"> <li>- Any kind of profitable, remunerated or involuntary donation of tissues and cells is prohibited (Art. 6(1)*).</li> <li>- Advertising the need for, or availability of human tissues and cells with a view to offering or seeking financial gain or comparable advantages is prohibited (Art. 6(2)*).</li> </ul> |
| <b>Describe the restrictions</b>  |  | Any activity relating to the promotion and advertising of donation of human tissues and cells must be in accordance with the guidelines and provisions which are determined by the Law.   |

\* Expected to be regulated through the implementation of the Quality and Safety Standards on Donation, Procurement, Testing, Processing, Preservation, Storage and Distribution of Human Tissues and Cells Law of 2006.

## VI. Additional comments

If you have any additional comments or information please fill out the box below:

The Ministry of Health of the Republic of Cyprus has continuously supported the voluntary donation and procurement of tissues and cells. It has supported the establishment of and has been funding the operation of Non-Governmental Organizations (NGOs) that promote the recruitment of volunteer donors and coordinate the collection and procurement of tissues and cells.

The Ministry of Health is the cofounder of the Karaiskakio Foundation, the NGO that is managing the Cyprus Bone Marrow Donor Registry (CYBMDR) on a non-profit basis. The Registry has more than 96,000 volunteer donors listed in the international registry (BMDW) located in Leiden. CYBMDR is the largest registry per capita in the world and the 5th largest in Europe.

The Ministry of Health has also recently organized in collaboration with the Karaiskakio Foundation and the Gynecological Society of Cyprus the first Public Cord Blood Registry. It also operates on a non-profit basis and the cord blood processing and cryopreservation laboratory is located in a public hospital.

Besides the financial support for the operating costs of the NGOs promoting the donation and procurement of tissues and cells the Ministry of Health organizes and participates in public awareness campaigns and related events.

# CZECH REPUBLIC

## I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>   | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>  |
|--|---|---|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | L   | L   |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  | Zákon č.285/2002 o darování, odběrech a transplantacích tkání a orgánů a o změně některých zákonů (transplantační zákon).<br>The Act No. 285/2002 on donation, harvests, and transplantations of tissues and organs and change of some other acts (Transplantation Act) | Zákon č.285/2002 o darování, odběrech a transplantacích tkání a orgánů a o změně některých zákonů (transplantační zákon)<br>The Act No.285/2002 on donation, harvests, and transplantations of tissues and organs and change of some other acts (Transplantation Act) |
| <b>3. Date of the regulation</b><br>(dd/mm/yyyy)   | 30.5 2002   | 30.5 2002   |
| <b>4. Entry into force of the regulation</b><br>(dd/mm/yyyy)   | 1.9 2002  | 1.9 2002  |

## II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|  | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b> |
|--|---|--|
| <b>1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?</b>  | NO  | NO   |
| <b>2. Where are the conditions defined under which compensation may be granted</b>   | L   | L  |
| <i>If this regulation is different from the one mentioned under question I, please indicate its title, date and date of entry into force</i> |   |  |

|   |   |   |
|---|---|---|
| <b>3. What does this compensation entail?</b> (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |   |   |
| a. Expense allowance<br>(please specify the type of expenses covered)   | <i>Travel expences<br/>-public transportation</i>                         | <i>Travel expences<br/>-public transportation</i>                         |
| b. Time off work<br>(please indicate duration)  | <i>Reimbursement of missed salary,maximum 92 hours</i>                    | <i>Reimbursement of missed salary,maximum 92 hours</i>                    |
| c. Compensation for discomfort endured<br>(please specify)  | <i>No</i>   | <i>No</i>   |
| d. Refreshments<br>(please specify)   | <i>Equivalent to blood donation</i>                                       | <i>Equivalent to blood donation</i>                                       |
| e. Others (please specify)  | <i>Tissues-No<br/>Cells- formalletter to donor and/or to the employer</i> | <i>tissues-No<br/>cells- formalletter to donor and/or to the employer</i> |
| f. If there are specific rules for certain types of tissues/cells, please specify   | <i>No</i>   | <i>No</i>   |
| <b>4. Are you aware of cases in your country where donors were given remuneration for the donation of tissues and cells?</b>  | NO<br><br>If you answered yes, please specify:                            |   |

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>   | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>  |
|---|--|--|
| <b>1. Have measures been taken to <u>promote donation of tissues and cells</u></b><br>(please tick the appropriate box)                 | YES  | YES  |
| <b>2. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, donor days, ...) | Only of haematopoetic cell<br>Information campaigns in the media are oriented especially to promote donation of haematopoetic cell (information campaigns, advertising, TV shots). Both public and private media are involved as well as foundations | Only of haematopoetic cell<br>Information campaigns in the media are oriented especially to promote donation of haematopoetic cell (information campaigns, advertising, TV shots). Both public and private media are involved as well as foundations |
| <b>3. Have measures been taken to <u>endeavour to ensure unpaid donation?</u></b>   | YES  | YES  |

|   |   |   |
|---|---|---|
| <p><b>4. Please describe the type of measures taken</b> (e.g. awareness raising or information campaigns, advertising, ...)</p> | <p>Act No. 285/2002<br/>The national network of cell and tissue banks licensed by the Ministry of Health was established after 1.st of September 2004. These banks must not provide any type of financial stimulation of donation. (Article 28)</p> | <p>Act No. 285/2002<br/>The national network of cell and tissue banks licensed by the Ministry of Health was established after 1.st of September 2004. These banks must not provide any type of financial stimulation of donation.( Article 28)</p> |
|---|---|---|

**IV. Promotion of the non-profit procurement of tissues and cells**

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|  | <p><b>Situation <u>before</u> the implementation of Directive 2004/23</b></p>   | <p><b>Situation <u>after</u> the implementation of Directive 2004/23</b></p>                        |
|--|---|---|
| <p><b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br/>(please tick the appropriate box)</p> | <p>YES</p>  | <p>YES</p>  |
| <p><b>2. Please describe the type of measures taken and the parties involved in their implementation</b></p>   | <p>Ministry of Health and it's Advisory Board named "The Cell and Tissue Transplant Committee".<br/>The Cell and Tissue Transplant Committee was established at the level of the Ministry of Health to collect data on donation, harvests and transplantations in the country and to issue the proposal of the National Policy in the field of cell and tissue transplantations based on voluntary and unpaid tissue donation and harvests made on non profit basis.<br/>The voluntary and unpaid donation as well as cell and tissue harvests made on no-profit basis are secured by a national network of cell and tissue banks licensed by the Ministry of Health.</p> | <p>Ministry of Health and it's Advisory Board named "The Cell and Tissue Transplant Committee".</p> |

## V. Advertising

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>   |
|---|---|---|
| <b>Do you have regulation providing for 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?</b><br>(please tick the appropriate box) | YES   | YES   |
| <b>Type of regulation</b> (please tick the appropriate box)   | L   | L   |
| <i>If this regulation is different from the one mentioned under question I, please indicate the title, date and date of entry into force of the regulation</i>  | The above mentioned Act as well as a change of An Offence Act made simultaneously with the approval of the Transplantation Act, Article 28  | The above mentioned Act as well as a change of An Offence Act made simultaneously with the approval of the Transplantation Act, Article 28  |
| <b>Describe the prohibitions</b>  | Advertising and dissemination of information on the availability of human cells and tissues to stimulate demand is prohibited. Offering of monetary compensation or similar advantages to stimulate the number of donors is prohibited. | Advertising and dissemination of information on the availability of human cells and tissues to stimulate demand is prohibited. Offering of monetary compensation or similar advantages to stimulate the number of donors is prohibited. |
| <b>Describe the restrictions</b>  | Act No 285/2002, Article 29<br>Penalty set a fine upon<br>-establishment of hospital up to 100 000 CZK<br>- legal ant personal entity up to 500 000 CZK   | Act No 285/2002, Article 29<br>Penalty set a fine upon<br>-establishment of hospital up to 100 000 CZK<br>- legal ant personal entity up to 500 000 CZK   |

## VI. Additional comments

If you have any additional comments or information please fill out the box below:

The majority issues mentioned in the questionnaire deal with the requirements of the Convention on Biomedicine and of the Additional Protocol. These requirements were implemented into the Low No. 285/2006 Transplantation Act approved in the year 2002 already.

# GERMANY

## I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>   | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>  |
|--|---|---|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | <b>L X</b><br>Für Gewebe und Blutstammzellen, mit Ausnahme von Knochenmark und embryonalen und fetalen Geweben; die Knochenmarkspende und die Spende von embryonalen und fetalen Gewebe sowie die Spende von menschlichen Zellen richtet sich nach den allgemeinen gesetzlichen Regelungen.<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N | <b>L X</b><br>Für Gewebe und Zellen (einschließlich Blutstammzellen, Knochenmark und embryonalen und fetalen Geweben und Zellen))<br><br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  | Transplantationsgesetz (TPG)<br>(The Transplantation Act)<br>§§ 17, 18 TPG<br>Transfusionsgesetz (Transfusion Act)<br>§ 10  | Art. 1 und 3 des Entwurfs eines Gewebegesetzes<br><br>Transfusion Act   |
| <b>3. Date of the regulation</b><br>(dd/mm/yyyy)   | 05 / 11 / 1997<br>01/07/1998  | 10/02/2005<br>(Amendment of the Transfusion Act)  |
| <b>4. Entry into force of the regulation</b><br>(dd/mm/yyyy)   | 01 / 12 /1997<br>07/07/1998   | 19/02/2005  |

## II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|  | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b> |
|--|---|--|
| <b>1. Are donors given any kind of <u>compensation</u></b> | <b>YES X</b> NO <input type="checkbox"/>  | <b>YES X</b> NO <input type="checkbox"/>   |

|   |   |   |
|---|---|---|
| <b>for the donation of tissues and cells?</b>   |   |   |
| <b>2. Where are the conditions defined under which compensation may be granted</b>  | <b>L X</b> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/><br>In § 17 TPG ist der Handel mit Organen, die einer Heilbehandlung zu dienen bestimmt sind, verboten. Das Organhandelsverbot gilt aufgrund der Legaldefinition in § 1 TPG auch für Organteile und Gewebe, mit Ausnahme von Knochenmark und embryonalen und fetalen Gewebe. Die Erstattung der spendebedingten Ausgaben und finanziellen Einbußen richtet sich unter Beachtung des Handelsverbots gemäß §§ 17, 18 TPG nach den allgemeinen gesetzlichen Regelungen. | <b>L X</b> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/><br>Im Art. 1 des Entwurfs des Gewebegesetzes wird im Hinblick auf die Erweiterung des Anwendungsbereichs für alle Organe und Gewebe, die einer medizinischen Behandlung zu dienen bestimmt sind, einschließlich Knochenmark und embryonale und fetale Gewebe oder Zellen, der Handel verboten. Die Erstattung der spendebedingten Ausgaben und finanziellen Einbußen richtet sich unter Beachtung des Handelsverbots gemäß §§ 17 und 18 TPG nach den allgemeinen gesetzlichen Regelungen. |
| <i>If this regulation is different from the one mentioned under question 1, please indicate its title, date and date of entry into force</i>  |   |   |
| <b>3. What does this compensation entail?</b> (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |   |   |
| a. Expense allowance (please specify the type of expenses covered)  | Siehe Antwort zu Frage 2.   | Siehe oben zu Frage 2.  |
| b. Time off work (please indicate duration)   | Richtet sich nach dem Einzelfall.   | Richtet sich nach dem Einzelfall.   |
| c. Compensation for discomfort endured (please specify)   | Grundsätzlich kein Ersatz.  | Grundsätzlich kein Ersatz.  |
| d. Refreshments (please specify)  | Siehe Antwort zu Frage 2.   | Siehe Antwort zu Frage 2.   |
| e. Others (please specify)  | Siehe Antwort zu Frage 2.   | Siehe Antwort zu Frage 2.   |
| f. If there are specific rules for certain types of tissues/cells, please specify   | Blutstammzellen: Verbot der entgeltlichen Spende. Aufwandsentschädigung für den Spender nach § 10 Transfusionsgesetz (richtet sich nach dem unmittelbaren Aufwand)  | Weiter differenzierte Regelung zur Aufwandsentschädigung in § 10 Transfusionsgesetz   |
| <b>4. Are you aware of cases in your country where donors were given remuneration for</b>   | YES <input type="checkbox"/> NO <b>X</b><br><br>If you answered yes, please specify:  |   |

|                                    |  |
|------------------------------------|--|
| the donation of tissues and cells? |  |
|------------------------------------|--|

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|   | Situation <u>before</u> the implementation of Directive 2004/23   | Situation <u>after</u> the implementation of Directive 2004/23      |
|---|---|---|
| <b>1. Have measures been taken to <u>promote donation</u> of tissues and cells</b><br>(please tick the appropriate box)                 | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> |
| <b>2. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, donor days, ...) | <p>Nach § 2 Abs. 1 TPG sind die nach Landesrecht zuständigen Stellen, die Bundesbehörden im Rahmen ihrer Zuständigkeit, insbesondere die Bundeszentrale für gesundheitliche Aufklärung (BZgA) sowie die Krankenkassen, verpflichtet, auf der Grundlage des TPG die Bevölkerung über die Möglichkeiten der Organ- und Gewebespende, die Voraussetzungen der Entnahme und die Bedeutung der Übertragung aufzuklären.</p> <p>Die Bundesregierung, insbesondere durch die BZgA, aktualisiert ständig ihr Informationsangebot und sorgt für eine breite Streuung. Die BZgA initiiert und unterstützt auch regionale, lokale und im alltäglichen Umfeld angesiedelte Projekte, Aktionen oder Veranstaltungen. Sie führt massenmedialen Maßnahmen mit großer Reichweite wie Anzeigen, Plakaten, Fernseh- und Kino-Spots durch und stellt Informationsmaterialien zur Verfügung. Es werden auch Projekte, die das persönliche Gespräch vor Ort möglich machen, veranstaltet</p> | <p>Die Verpflichtung zur Aufklärung besteht fort.</p>               |

|  |  |   |
|--|--|---|
|  | z.B.: Info-telefon Organ-spende in Kooperation mit der Deutschen Stiftung Organtransplantation (DSO).  |   |
| <b>3. Have measures been taken to <u>endeavour to ensure unpaid donation</u>?</b>  | <b>YES X</b> <b>NO <input type="checkbox"/></b>  | <b>YES X</b> <b>NO <input type="checkbox"/></b>   |
| <b>4. Please describe the type of measures taken</b> (e.g. awareness raising or information campaigns, advertising, ...) | Die Verpflichtung zur Aufklärung nach § 2 Abs. 1 TPG erstreckt sich auch auf das nach §§ 17, 18 TPG geltende Organ- und Gewebehandelsverbots, das auch der Handel mit Geweben mit Ausnahme von Knochenmark und embryonalen und fetalen Gewebe erfasst. | Die Verpflichtung zur Aufklärung besteht fort. Diese erstreckt sich auf das weiterhin bestehende Organ- und Gewebehandelsverbotes, das auch das Verbot des Handels mit menschlichen Zellen erfasst. |

#### IV. Promotion of the non-profit procurement of tissues and cells

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|  | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>                 | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>                      |
|--|--|--|
| <b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br><br>(please tick the appropriate box) | <b>YES X</b> <b>NO <input type="checkbox"/></b>  | <b>YES X</b> <b>NO <input type="checkbox"/></b>  |
| <b>2. Please describe the type of measures taken and the parties involved in their implementation</b>  | Vgl. Antwort zu Fragen III. Im übrigen gilt das Organhandelsverbot nach §§ 17, 18 TPG: | Vgl. Antwort zu Fragen III. Im übrigen wird das Organ- und Gewebehandelsverbot fortgelten: |

#### V. Advertising

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation <u>after</u> the implementation of Directive 2004/23</b> |
|---|--|---|
| <b>Do you have regulation providing for restrictions or prohibitions on advertising the need for,</b> | <b>YES X</b> <b>NO <input type="checkbox"/></b>                        | <b>YES X</b> <b>NO <input type="checkbox"/></b>                       |

|  |   |   |
|--|---|---|
| <p><b>or availability of human tissues and cells with a view to offering or seeking financial gain or comparable advantages?</b><br/>(please tick the appropriate box)</p> |   |   |
| <p><b>Type of regulation</b> (please tick the appropriate box)</p>   | <p><b>L X</b>    G <input type="checkbox"/>    GNO <input type="checkbox"/></p>   | <p><b>L X</b>    G <input type="checkbox"/>    GNO <input type="checkbox"/></p>   |
| <p><i>If this regulation is different from the one mentioned under question I, please indicate the title, date and date of entry into force of the regulation</i></p>      |   |   |
| <p><b>Describe the prohibitions</b></p>  | <p>Das Verbot des Handeltreibens nach § 17 TPG erfasst auch die Werbung, mit der zum Ausdruck gebracht wird, dass mit den Organen und Geweben Handel betrieben werden soll, z.B. durch ein ernsthaftes und verbindliches Verkaufs- oder Kaufsangebot. Nach § 18 TPG ist diese Werbung strafbar.</p> | <p>Auch das Verbot des Handeltreibens wird sich wie bisher auf ein Werbeverbot erstrecken, mit dem zum Ausdruck gebracht wird, dass mit den Organen und Geweben, einschließlich Zellen, kein Handel betrieben werden soll, z.B. durch ein ernsthaftes und verbindliches Verkaufs- oder Kaufsangebot. Diese Werbung wird weiterhin strafbar sein.</p> <p>Auch ist es verboten und strafbar, für Gewebe- und Zellspender mit der Zahlung einer finanziellen Zuwendung oder oder Aufwandsentschädigung zu werben (§ 7 Abs. 3 Heilmittelwerbegesetz, geändert durch das o.g. Gesetz vom 10/02/05)</p> |
| <p><b>Describe the restrictions</b></p>  | <p>Siehe oben.</p>  | <p>Siehe oben.</p>  |

**VI. Additional comments**

If you have any additional comments or information please fill out the box below:

# DENMARK

## I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>     |
|--|--|--|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | X <input type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N   | X <input type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  | Sundhedslovens (Act of Health) § 268 (2), which – in an unofficial translation – reads:<br><i>“Anyone, who offers or receives payment or other economic benefit for the procurement or transfer of tissues or other biological material [...] is punishable by fine. The same applies to anyone, who, knowing that such payment has been offered or received [...] assists in the carrying out of such an intervention”.</i> | Unchanged  |
| <b>3. Date of the regulation</b><br>(dd/mm/yyyy)   | § 268 (2) in the Act of Health entered into force in June 2005. However, § 268 (2) in the Act of Health is identical with § 20 (3) in a previous law from 1990.  | Unchanged  |
| <b>4. Entry into force of the regulation</b><br>(dd/mm/yyyy)   | See above.   | -  |

## II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|   | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b> |
|---|---|--|
| <b>1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?</b> | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>                               | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>  |

|   |  |  |
|---|--|--|
| <b>2. Where are the conditions defined under which compensation may be granted</b>  | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input checked="" type="checkbox"/>   | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input checked="" type="checkbox"/> |
| <i>If this regulation is different from the one mentioned under question 1, please indicate its title, date and date of entry into force</i>  |  |  |
| <b>3. What does this compensation entail?</b> (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |  |  |
| a. Expense allowance (please specify the type of expenses covered)  | Would be considered acceptable as regards <u>documented</u> expenses.  | <i>Same</i>  |
| b. Time off work (please indicate duration)   | Would be considered acceptable, if <u>documented</u> . However, the situation would rarely – if ever – arise, e.g. with bone marrow (in house patients) or cornea (deceased donors). And sperm donors (which are not specifically covered by this survey) are very often students. | <i>Same</i>  |
| c. Compensation for discomfort endured (please specify)   | Would be considered acceptable. However, the National Board of Health is not aware that this practice is generally employed (disregarding sex cells, which are not specifically covered by this survey – sperm donors receive a modest compensation of approx. 500 Danish kroner). | <i>Same</i>  |
| d. Refreshments (please specify)  | Would be considered acceptable – e.g. juice, coffee, tea. Also occurs in practice, but not to an extent which exceeds common hospitality.  | <i>Same</i>  |
| e. Others (please specify)  |  |  |
| f. If there are specific rules for certain types of tissues/cells, please specify   |  |  |
| <b>4. Are you aware of cases in your country where donors were given <u>remuneration</u> for the donation of tissues and cells?</b>   | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/><br><br>If you answered yes, please specify:  |  |

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>   | <b>Situation <u>after</u> the implementation of Directive 2004/23</b> |
|---|--|---|
| <b>1. Have measures been taken to <u>promote donation of tissues and cells</u></b><br>(please tick the appropriate box)                 | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>  | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>   |
| <b>2. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, donor days, ...) | Awareness raising information campaigns, booklets, electronic access to register as a donor. All are public initiatives. | No new measures have been taken.                                      |
| <b>3. Have measures been taken to <u>endeavour to ensure unpaid donation?</u></b>   | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>  | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>   |
| <b>4. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, ...)             |  |   |

### IV. Promotion of the non-profit procurement of tissues and cells

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|  | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>   |
|--|---|---|
| <b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br>(please tick the appropriate box) | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/><br><br>(I.e. not apart from the legislation, cf. I.2) | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/><br><br>(I.e. not apart from the legislation, cf. I.2) |

|   |  |  |
|---|--|--|
| <b>2. Please describe the type of measures taken and the parties involved in their implementation</b> |  |  |
|---|--|--|

**V. Advertising**

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>   | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>              |
|---|--|--|
| <b>Do you have regulation providing for 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?</b><br>(please tick the appropriate box) | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>  | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>                |
| <b>Type of regulation</b> (please tick the appropriate box)   | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/>   | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> |
| <i>If this regulation is different from the one mentioned under question I, please indicate the title, date and date of entry into force of the regulation</i>  | The Law on marketing of Health Services prohibits the marketing of health services on TV, film, video or the like. The use of false or misleading information in the marketing of such services is also prohibited by this law. However, this does not specifically address the topic mentioned above. |  |
| <b>Describe the prohibitions</b>  |  |  |
| <b>Describe the restrictions</b>  |  |  |

**VI. Additional comments**

If you have any additional comments or information please fill out the box below:

|  |
|--|
|  |
|--|

# ESTONIA

### I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|   | Situation in the national regulation <u>before</u> the implementation of Directive 2004/23  | Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23   |
|---|---|---|
| 1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?<br>(please tick the appropriate box) | X L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N   | X L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N   |
| 2. Title of the regulation<br>(please add the full title and if possible an English translation)  | 1) Elundite ja kudede siirdamise seadus<br>Transplantation of Organs and Tissues Act<br>2) Kunstliku viljastamise ja embrüokaitse seadus<br>Artificial Insemination and Embryo Protection Act | 1) Elundite ja kudede siirdamise seadus<br>Transplantation of Organs and Tissues Act<br>2) Kunstliku viljastamise ja embrüokaitse seadus<br>Artificial Insemination and Embryo Protection Act |
| 3. Date of the regulation<br>(dd/mm/yyyy)   | 1) 30.01.2002<br>2) 11.06.1997  | 1) – 2) introduction of changes<br>2006 December  |
| 4. Entry into force of the regulation<br>(dd/mm/yyyy)   | 1) 04.03.2002<br>2) 17.07.1997  | 1) – 2) 2007 January  |

### II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, donors cannot be remunerated, but they may receive compensation (making good the expenses and inconveniences related to the donation).

|  | Situation in the national regulation <u>before</u> the implementation of Directive 2004/23 | Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23 |
|--|--|---|
| 1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?   | YES X      NO <input type="checkbox"/>   | YES X      NO <input type="checkbox"/>  |
| 2. Where are the conditions defined under which compensation may be granted  | L x   G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/>   | L x   G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/>                      |
| <i>If this regulation is different from the one mentioned under question 1, please indicate its title, date and date of entry into force</i>   | Artificial Insemination and Embryo Protection Act  | Artificial Insemination and Embryo Protection Act   |
| 3. What does this compensation entail? (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |  |   |

|  |   |  |
|--|---|--|
| a. Expense allowance<br>(please specify the type of expenses covered)  |   |  |
| b. Time off work<br>(please indicate duration)   |   |  |
| c. Compensation for discomfort endured<br>(please specify)   |   |  |
| d. Refreshments<br>(please specify)  |   |  |
| e. Others (please specify)   |   |  |
| f. If there are specific rules for certain types of tissues/cells, please specify  | A donor has the right to compensation for gamete donation.                |  |
| 4. Are you aware of cases in your country where donors were given <u>remuneration</u> for the donation of tissues and cells? | YES <input type="checkbox"/> NO X<br>If you answered yes, please specify: |  |

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|   | Situation <u>before</u> the implementation of Directive 2004/23 | Situation <u>after</u> the implementation of Directive 2004/23 |
|---|---|--|
| 1. Have measures been taken to <u>promote donation</u> of tissues and cells<br>(please tick the appropriate box)              | YES <input type="checkbox"/> NO x                               | YES <input type="checkbox"/> NO x                              |
| 2. Please describe the type of measures taken (e.g. awareness raising or information campaigns, advertising, donor days, ...) |   |  |
| 3. Have measures been taken to <u>endeavour to ensure unpaid donation</u> ?   | YES <input type="checkbox"/> NO x                               | YES <input type="checkbox"/> NO x                              |
| 4. Please describe the type of measures taken (e.g. awareness raising or information campaigns, advertising, ...)             |   |  |

#### IV. Promotion of the non-profit procurement of tissues and cells

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|   | Situation <u>before</u> the implementation of Directive 2004/23     | Situation <u>after</u> the implementation of Directive 2004/23      |
|---|---|---|
| 1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?<br>(please tick the appropriate box) | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> |
| 2. Please describe the type of measures taken and the parties involved in their implementation  |   |   |

#### V. Advertising

|  | Situation <u>before</u> the implementation of Directive 2004/23  | Situation <u>after</u> the implementation of Directive 2004/23                                |
|--|--|---|
| Do you have regulation providing for 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?<br>(please tick the appropriate box) | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>  | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>                           |
| Type of regulation (please tick the appropriate box)   | L <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/>  | L <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> |
| <i>If this regulation is different from the one mentioned under question I, please indicate the title, date and date of entry into force of the regulation</i>   | Advertising Act 11.06.1997.<br>Entered into force:<br>01.01.1998<br>Artificial Insemination and Embryo Protection Act  |   |
| Describe the prohibitions  | Advertising for artificial insemination is prohibited. A provider of specialised medical care who organises artificial insemination has the right to provide information concerning artificial insemination in the press and take the measures |   |

|                           |   |  |
|---------------------------|---|--|
|                           | necessary for finding donors.   |  |
| Describe the restrictions | The advertising of health services may include only the name, working time, place of business and speciality of the health care provider, the names, specialties and academic degrees of health care professionals, and the health services provided. |  |

VI. Additional comments

If you have any additional comments or information please fill out the box below:

# SPAIN

## I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | Situation in the national regulation <u>before</u> the implementation of Directive 2004/23  | Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23                     |
|--|---|---|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | <input checked="" type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N | <input checked="" type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  | Ley de Trasplantes 30/1979.<br>Real Decreto 411/1996.<br>R.D. del año 1999.   | 1979<br>1996<br>2000  |
| <b>3. Date of the regulation</b><br>(dd/mm/yyyy)   | 1979<br>1996<br>1999  |   |
| <b>4. Entry into force of the regulation</b><br>(dd/mm/yyyy)   |   | R.D. Células y Tejidos 2006   |

## II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|   | Situation in the national regulation <u>before</u> the implementation of Directive 2004/23                               | Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23            |
|---|--|--|
| <b>1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?</b>   | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO  | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO  |
| <b>2. Where are the conditions defined under which compensation may be granted</b>  | <input checked="" type="checkbox"/> L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N | <input checked="" type="checkbox"/> L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N |
| <i>If this regulation is different from the one mentioned under question 1, please indicate its title, date and date of entry into force</i>  |  |  |
| <b>3. What does this compensation entail?</b> (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |  |  |
| a. Expense allowance<br>(please specify the type of expenses covered)   | <i>No específicamente</i>  |  |
| b. Time off work<br>(please indicate duration)  | <i>Si, en caso de autónomos que no perciben base laboral.</i>  | <i>Si, en caso de autónomos que no perciben base laboral</i>   |

|   |  |   |
|---|--|---|
| c. Compensation for discomfort endured (please specify)   | <i>Baja laboral, si procede</i>  | <i>Baja laboral, si procede</i>             |
| d. Refreshments (please specify)  | <i>Dietas de Alojamiento si se desplaza</i>  | <i>Dietas de Alojamiento si se desplaza</i> |
| e. Others (please specify)  | <i>Ttransporte</i>   | <i>Ttransporte</i>                          |
| f. If there are specific rules for certain types of tissues/cells, please specify   | <i>NO</i>  | <i>NO</i>                                   |
| <b>4. Are you aware of cases in your country where donors were given <u>remuneration</u> for the donation of tissues and cells?</b> | YES <input type="checkbox"/> <b>NO <input checked="" type="checkbox"/></b><br>If you answered yes, please specify: |   |

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>  |
|---|---|--|
| <b>1. Have measures been taken to <u>promote donation</u> of tissues and cells</b><br>(please tick the appropriate box)                 | <b>YES <input checked="" type="checkbox"/></b> NO <input type="checkbox"/><br>Plan Nacional Promoción Donación  | <b>YES <input checked="" type="checkbox"/></b> NO <input type="checkbox"/><br>Plan Nacional Promoción Donación |
| <b>2. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, donor days, ...) | <ul style="list-style-type: none"> <li>-Promoción e información a la sociedad en general.</li> <li>-Grupos específicos (jueces, forenses, medios de comunicación, minorías.</li> <li>-Promoción en el ámbito sanitario.</li> <li>-Cursos de perfeccionamiento de técnicas de comunicación.</li> <li>-Campañas.</li> <li>-Día del donante.</li> <li>-Entrenamiento específico de Coordinadores.</li> </ul> | Lo mismo.  |
| <b>3. Have measures been taken to <u>endeavour to ensure unpaid donation</u>?</b>   | <b>YES <input checked="" type="checkbox"/></b> NO <input type="checkbox"/>  | <b>YES <input checked="" type="checkbox"/></b> NO <input type="checkbox"/>                                     |
|   | -Los Trasplantes y las donaciones se hacen de acuerdo a los mismos estándares en el sistema público y en el privado.  | Lo mismo.  |

|  |  |  |
|--|--|--|
|  | <p>-No puede haber comunicación entre donantes y receptores.</p> <p>-La donación de vivo está regulada y protege al Donante</p> <p>-No pueden ser donantes en vida los menores o incapacitados con excepciones muy concretas</p> |  |
|--|--|--|

#### IV. Promotion of the non-profit procurement of tissues and cells

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|  | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>                  |
|--|---|--|
| <p><b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br/>(please tick the appropriate box)</p> | <p><b>YES</b> <input checked="" type="checkbox"/>      NO <input type="checkbox"/></p>  | <p><b>YES</b> <input checked="" type="checkbox"/>      NO <input type="checkbox"/></p> |
| <p><b>2. Please describe the type of measures taken and the parties involved in their implementation</b></p>   | <p>-Banco de Tejidos públicos y/o de titularidad sin ánimo de lucro.</p> <p>-No se podrá percibir compensación alguna por la donación de tejidos humanos ni existirá compensación económica para el donante, ni cualquier otra persona, salvo lo previsto en el apartado 3. del presente artículo. No se exigirá al receptor precio alguno por el tejido implantado.</p> <p>-No obstante, deberá garantizarse al donante vivo la asistencia precisa para su restablecimiento.</p> <p>-Las actividades desarrolladas por los Bancos de Tejidos Humanos serán sin ánimo de lucro, debiendo existir exclusivamente la compensación de los gastos derivados de su actividad.</p> <p>- Las entradas y salidas de</p> |  |

|  |  |  |
|--|--|--|
|  | tejidos del Territorio Español se realizan a través de estos Bancos. |  |
|--|--|--|

### V. Advertising

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>   | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>                                |
|---|--|--|
| <b>Do you have regulation providing for 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?</b><br>(please tick the appropriate box) | <b>YES</b> <input checked="" type="checkbox"/> NO <input type="checkbox"/>   | <b>YES</b> <input checked="" type="checkbox"/> NO <input type="checkbox"/>                           |
| <b>Type of regulation</b> (please tick the appropriate box)   | <b>L</b> <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/>                     | <b>L</b> <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> |
| <b>Describe the prohibitions</b>  | -Se prohíbe la publicidad de la donación de tejidos en beneficio de personas concretas, o bancos de tejidos determinados | Lo mismo   |
| <b>Describe the restrictions</b>  |  |  |

### VI. Additional comments

If you have any additional comments or information please fill out the box below:

|  |
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# FINLAND

## I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>                           |
|--|--|--|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | X L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N  | X L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N  |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  | Laki ihmisen elimien ja kudoksien lääketieteellisestä käytöstä (101/2001)<br>Act on the Medical Use of Human Organs and Tissues (No. 101/2001) | Laki ihmisen elimien ja kudoksien lääketieteellisestä käytöstä (101/2001)<br>Act on the Medical Use of Human Organs and Tissues (No. 101/2001) |
| <b>3. Date of the regulation</b><br>(dd/mm/yyyy)   | 02/02/2001   | No need to amend the existing provisions as regards voluntary and unpaid donation  |
| <b>4. Entry into force of the regulation</b><br>(dd/mm/yyyy)   | 01/09/2001   | Draft bill to amend the above mentioned Act will be issued to the Parliament in the early autumn 2006  |

## II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|  | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b> |
|--|---|--|
| <b>1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?</b>  | YES X                      NO <input type="checkbox"/>  | YES X                      NO <input type="checkbox"/>   |
| <b>2. Where are the conditions defined under which compensation may be granted</b>   | L X   G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/>          | L X   G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/>                             |
| <i>If this regulation is different from the one mentioned under question I, please indicate its title, date and date of entry into force</i> |   |  |

|   |  |                       |
|---|--|-----------------------|
| <b>3. What does this compensation entail?</b> (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |  |                       |
| a. Expense allowance<br>(please specify the type of expenses covered)   |  |                       |
| b. Time off work<br>(please indicate duration)  |  |                       |
| c. Compensation for discomfort endured<br>(please specify)  |  |                       |
| d. Refreshments<br>(please specify)   |  |                       |
| e. Others (please specify)  | It is enacted in the Act No. 101/2001, section 18, that:<br>“The donor of an organ or tissue who suffers lack of income for a whole day because of removal of an organ or tissue as referred to in this Act to meet a vital transplantation need or for essential related tests and examinations, and does not get paid or receive corresponding compensation for this period, is entitled to a daily allowance as provided concerning daily allowance in the Sickness Insurance Act (364/1963). The daily allowance will be paid for every weekday notwithstanding section 19 of the said Act.” | No amendments planned |
| f. If there are specific rules for certain types of tissues/cells, please specify   |  |                       |
| <b>4. Are you aware of cases in your country where donors were given remuneration for the donation of tissues and cells?</b>  | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/><br><br>If you answered yes, please specify:  |                       |

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>   |
|---|---|---|
| <b>1. Have measures been taken to <u>promote donation of tissues and cells</u></b><br>(please tick the appropriate box)                 | YES X                      NO <input type="checkbox"/>  | YES X                      NO <input type="checkbox"/>  |
| <b>2. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, donor days, ...) | Awareness raising e.g. through patient associations. Local initiatives to improve procurement of tissues and cells. | Awareness raising e.g. through patient associations. Local initiatives to improve procurement of tissues and cells. |
| <b>3. Have measures been taken to <u>endeavour to ensure unpaid donation?</u></b>   | YES <input type="checkbox"/> NO X<br>(because of the legislation in force)  | YES <input type="checkbox"/> NO X<br>(because of the legislation in force)  |
| <b>4. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, ...)             |   |   |

### IV. Promotion of the non-profit procurement of tissues and cells

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|  | <b>Situation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation <u>after</u> the implementation of Directive 2004/23</b> |
|--|--|---|
| <b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br>(please tick the appropriate box) | YES X                      NO <input type="checkbox"/>                 | YES X                      NO <input type="checkbox"/>                |
| <b>2. Please describe the</b>  | It is enacted in the Act No.   | No amendments planned   |

|  |   |  |
|--|---|--|
| <b>type of measures taken and the parties involved in their implementation</b> | 101/2001, section 18, that:<br>“A health care unit or other unit involved in removing, retaining, storing or using organs and tissue may not pursue financial gain from the activities provided for in this Act. However, the health care unit or other unit may charge another health care unit for handling and transporting organs and tissues, and for carrying out the tests needed to ensure safety and for providing storage. The charge made may not exceed the total cost of producing the service.” |  |
|--|---|--|

**V. Advertising**

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>                     | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>                      |
|---|--|--|
| <b>Do you have regulation providing for 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?</b><br>(please tick the appropriate box) | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> X<br>(see question IV) | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> X<br>(see question IV) |
| <b>Type of regulation</b> (please tick the appropriate box)   | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/>         | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/>         |
| <i>If this regulation is different from the one mentioned under question I, please indicate the title, date and date of entry into force of the regulation</i>  |  |  |
| <b>Describe the prohibitions</b>  |  |  |

|                                  |  |  |
|----------------------------------|--|--|
| <b>Describe the restrictions</b> |  |  |
|----------------------------------|--|--|

#### VI. Additional comments

If you have any additional comments or information please fill out the box below:

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|--|

# FRANCE

(two reports received)

### I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>              |
|--|--|---|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | <input checked="" type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N  | <input checked="" type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  | LOI no 94-654 du 29 juillet 1994 relative au don et à l'utilisation des éléments et produits du corps humain, à l'assistance médicale à la procréation et au diagnostic prénatal | Loi 2004/800 du 6 août 2004 relative à la bioéthique  |
| <b>3. Date of the regulation</b>   | 29/07/1994   | 07/08/2004  |
| <b>4. Entry into force of the regulation</b><br>(  | 30/07/1994   | 07/08/2004 pour les principes éthiques (application différée pour d'autres mesures nécessitant des dispositions réglementaires)   |

### II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|   | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>   |
|---|--|--|
| <b>1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?</b> | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/><br><b>Art L. 1211-4</b> : Aucun paiement, quelle qu'en soit la forme, ne peut être alloué à celui qui se prête au prélèvement d'éléments de son corps ou à la collecte de ses produits.<br>Seul peut intervenir le cas échéant le remboursement des frais engagés. | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/><br><b>Art L. 1211-4</b> : Aucun paiement, quelle qu'en soit la forme, ne peut être alloué à celui qui se prête au prélèvement d'éléments de son corps ou à la collecte de ses produits.<br><b>Les frais afférents au prélèvement et à la collecte sont intégralement pris en charge par l'établissement de santé chargé d'effectuer le prélèvement ou la collecte.</b><br><b>Pour l'application des dispositions du chapitre II du titre IV du livre Ier de la première partie du présent code, le prélèvement d'organes, de tissus ou de cellules sur une personne vivante qui en fait le</b> |

|  |   |   |
|--|---|---|
|  |   | <p><b>don dans l'intérêt thérapeutique d'un receveur est assimilé à un acte de soins.</b></p> <p><i>(Le principe éthique a été renforcé sur 2 points :</i></p> <p><i>- Le 2<sup>ème</sup> alinéa permet d'une part la prise en charge directe par l'établissement préleveur de certains frais afférents au prélèvement afin de dispenser le donneur de leur avance et d'autre part la prise en charge des frais engagés pendant l'étape de sélection du donneur.</i></p> <p><i>- Le 3<sup>ème</sup> alinéa permet aux personnes qui se prêtent à un prélèvement d'organes, de tissus ou de cellules dans l'intérêt thérapeutique d'un receveur de bénéficier du dispositif d'indemnisation des accidents médicaux mis en place par le titre IV de la loi du 4 mars 2002 relatif aux droits des malades et à la qualité du système de santé.</i></p> <p>--</p> |
| R  | L <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/><br>Décret n°2000-409 du 11/05/2000 relatif remboursement des frais engagés à l'occasion du prélèvement d'éléments du corps humain  | L <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/><br>Décret n°2000-409 DU 11/05/2000 relatif remboursement des frais engagés à l'occasion du prélèvement du corps humain   |
| <p><i>If this regulation is different from the one mentioned under question 1, please indicate its title, date and date of entry into force</i></p>  |   |   |
| <p><b>3. What does this compensation entail? (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.)</b></p> |   |   |
| <p>a. Expense allowance (please specify the type of expenses covered)</p>  | <p>1) pour les donneurs vivant</p> <p>a) Prise en charge :</p> <ul style="list-style-type: none"> <li>- des frais de transport</li> <li>- des frais d'hébergement (hormis hospitalisation)</li> <li>- des frais d'examen et de traitement prescrits en vue du prélèvement</li> <li>- des frais d'analyses de biologie médicale (dépistage des maladies infectieuses)</li> <li>- des frais d'hospitalisation</li> </ul> <p>b) indemnisation de la perte de rémunération subie par le donneur</p> <p>2) pour les donneurs décédés</p> | <p><i>Pas de changement sur les principes fondamentaux. Toutefois, ce texte est en cours de révision pour clarifier certains circuits de prise en charge financière (entre les établissements de santé et les caisses d'assurance-maladie notamment) et pour améliorer la prise en charge des donneurs après le prélèvement (mise en place d'une indemnisation pour perte de rémunération pour les donneurs en situation d'invalidité suite au prélèvement).</i></p>  |

|  |   |                            |
|--|---|----------------------------|
|  | Prise en charge :<br><ul style="list-style-type: none"> <li>- des frais de transport d'un établissement de santé vers un autre établissement de santé en vue d'établir le diagnostic de mort encéphalique et d'effectuer des prélèvements à des fins thérapeutiques</li> <li>- des frais de conservation et de restauration du corps après l'acte de prélèvement</li> </ul> |                            |
| b. Time off work (please indicate duration)  | Durée de l'hospitalisation  | Durée de l'hospitalisation |
| c. Compensation for discomfort endured (please specify)  | Non mentionné   | Non mentionné              |
| d. Refreshments (please specify)   | Non mentionné   | Non mentionné              |
| e. Others (please specify)   | Non mentionné   | Non mentionné              |
| f. If there are specific rules for certain types of tissues/cells, please specify  | Non mentionné   | Non mentionné              |
| <b>4. Are you aware of cases in your country where donors were given remuneration for the donation of tissues and cells?</b> | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/><br>If you answered yes, please specify:   |                            |

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|  | <b>Situation before the implementation of Directive 2004/23</b>   | <b>Situation after the implementation of Directive 2004/23</b>  |
|--|---|---|
| <b>1. Have measures been taken to promote donation of tissues and cells</b><br>(please tick the appropriate box) | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/><br><b>CODE DE LA SANTE PUBLIQUE</b><br><br><b>ART.L.1251-1</b> : L'Etablissement français des greffes est en outre chargé de promouvoir le don d'organes, de moelle, de cornée ou d'autres tissus en participant à l'information du public<br><b>ART L.1211-3</b> : l'information du public en faveur du don d'éléments et de produits du corps humain est réalisée sous la responsabilité du ministre chargé de la santé | <input checked="" type="checkbox"/> NO<br><b>1) CODE DE LA SANTE PUBLIQUE</b><br><br><b>ART L.1418-1 (alinéa 5)</b><br><b>L'Agence de la biomédecine</b> a pour mission de promouvoir le don d'organes, de tissus et de cellules issus du corps humain ainsi que le don de gamètes<br><b>ART L.1211-3</b> : l'information du public en faveur du don d'éléments et de produits du corps humain est réalisée sous la responsabilité du ministre chargé de la santé, en collaboration avec le ministre chargé de l'éducation nationale.<br><b>Les médecins s'assurent que leurs patients âgés de seize à vingt-cinq ans sont informés des modalités de consentement au don d'organes à fins de greffe et,</b> |

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|   |   | <p>à défaut, leur délivrent individuellement cette information dès que possible.</p> <p><b>2) CODE DU SERVICE NATIONAL</b></p> <p><b>Art L.114-3 : Lors de l'appel de préparation à la défense, ...il est délivré une information sur les modalités de consentement au don d'organes à fins de greffe et sur les possibilités pour une personne d'inscrire son refus sur le registre natinal automatisé prévu à l'article L.1232-1 du code de la santé publique.</b></p> <p><i>(La promotion du don est renforcé à travers l'information des jeunes par 3 mesures complémentaires :</i></p> <ul style="list-style-type: none"> <li>- <i>le ministre de l'Education Nationale est associé à cette information</i></li> <li>- <i>les jeunes revevront une information lors de la journée d'appel à la défense</i></li> <li>- <i>les médecins devront informer les jeunes de 16 à 25 ans.)</i></li> </ul> |
| <p><b>2. Please describe the type of measures taken</b> (e.g. awareness raising or information campaigns, advertising, donor days, ...)</p> | <ul style="list-style-type: none"> <li>- campagnes d'information du grand public sur le don d'organes et la greffe organisées par l'Agence de biomédecine et les associations en faveur de la greffe</li> <li>- journée nationale de reflexion sur le don d'orgnes et la greffe qui a lieu chaque année le 22 juin et qui repose sur : <ul style="list-style-type: none"> <li>• une importante mobilisation de la presse écrite et des médias (cinéma –TV- radio )</li> <li>• des manifestations organisées dans toutes les villes sur le thème du don et de la greffe</li> <li>• des affiches dans les lieux publics où il y a un passage important (métro par exemple) et des brochures d'information distribués sur les lieux des</li> </ul> </li> </ul> | <p>Ces actions sont les mêmes. Elles s'inscriront à compter de cette année dans le cadre d'une charte du don permettant de mieux renforcer la coopération entre les agences et les associations dans leurs actions de promotion du don.</p>  |

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|  | <p>manifestations</p> <ul style="list-style-type: none"> <li>- campagnes d'information de l'Agence de la biomedecine à l'attention des professionnels de santé par le biais de réunions et de documents distribués dans les établissements hospitaliers</li> <li>- campagnes de sensibilisation ciblés sur certains publics (intervention d'enseignants en biologie, en médecine ou en sciences de la vie et de la terre auprès d'étudiants, de lycéens et de collégiens)</li> <li>- Participation de la France aux jeux mondiaux des transplantés</li> </ul>  |   |
| <p><b>3. Have measures been taken to <u>endeavour to ensure unpaid donation?</u></b></p> | <p>YES <input checked="" type="checkbox"/> NO <input type="checkbox"/></p> <p><b>1) Principes généraux</b><br/> <b>Art. L. 1211-4.</b> - Aucun paiement, quelle qu'en soit la forme, ne peut être alloué à celui qui se prête au prélèvement d'éléments de son corps ou à la collecte de ses produits.</p> <p><b>Art L.1211-3 :</b> La publicité en faveur d'un don d'éléments ou de produits du corps humain au profit d'une personne déterminée ou au profit d'un établissement ou organisme déterminé est interdite. Cette interdiction ne fait pas obstacle à l'information du public en faveur du don d'éléments et de produits du corps humain.</p> <p><b>2) Mise en place de sanctions pénales en cas d'infraction à la règle du don non rémunéré.</b><br/> <b>Article L1272-1</b><br/> Comme il est dit à l'article 511-2 du code pénal ci-après reproduit :<br/> « Le fait d'obtenir d'une personne l'un de ses organes contre un paiement, quelle qu'en soit la forme, est puni de sept ans d'emprisonnement et de 100000 euros d'amende.<br/> Est puni des mêmes peines le fait d'apporter son entremise pour favoriser l'obtention d'un organe contre le paiement de celui-ci, ou de céder à titre onéreux un tel organe du corps d'autrui.<br/> Les mêmes peines sont applicables dans le cas où l'organe obtenu dans les conditions prévues au premier alinéa provient d'un pays étranger.</p> | <p>YES <input checked="" type="checkbox"/> NO <input type="checkbox"/></p> <p><b>1) Principes généraux inchagés</b></p> <p><b>2) Pas de changement. Ces sanctions pénales sont maintenues</b></p> |

|  |   |  |
|--|---|--|
|  | <p style="text-align: center;"><b>Article L1272-3</b></p> <p>Comme il est dit à l'article 511-4 du code pénal ci-après reproduit :<br/> « Le fait d'obtenir d'une personne le prélèvement de tissus, de cellules ou de produits de son corps contre un paiement, quelle qu'en soit la forme, est puni de cinq ans d'emprisonnement et de 75000 euros d'amende.<br/> Est puni des mêmes peines le fait d'apporter son entremise pour favoriser l'obtention de tissus, de cellules ou de produits humains contre un paiement, quelle qu'en soit la forme, ou de céder à titre onéreux des tissus, des cellules ou des produits du corps d'autrui. »</p> |  |
|--|---|--|

**IV. Promotion of the non-profit procurement of tissues and cells**

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|   | <b>Situation before the implementation of Directive 2004/23</b>   | <b>Situation after the implementation of Directive 2004/23</b>  |
|---|---|---|
| <p><b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br/>         (please tick the appropriate box)</p> | <p>YES <input checked="" type="checkbox"/> NO <input type="checkbox"/></p> <p>1) code de déontologie médicale et statut des praticiens hospitaliers (impossibilité pour le corps médical de percevoir des rémunérations, indemnités ou honoraires autres que ceux prévus par la loi )</p> <p>2) Infractions pénales (voir articles L.1272-1 et L.1272-3 mentionnés ci-dessus)</p> <p>3) Mise en place d'un corps d'inspection chargé de signaler tout manquement aux règles en vigueur</p> <p><b>Article L. 5313-3</b> : L'agence française de sécurité sanitaire des produits de santé désigne, parmi ses agents, des inspecteurs qui contrôlent l'application des lois et règlements relatifs aux activités et aux produits mentionnés à l'article L. 5311-1. <i>(parmi ces produits figurent les tissus et les cellules)</i></p> | <p>YES <input type="checkbox"/> NO <input type="checkbox"/></p> <p>Pas de changement : ces dispositions sont maintenues</p> |
| <p><b>Please describe the type of measures and the parties involved in their implantation</b></p>   | <p>Inspections pratiquées dans les établissements de santé dans lesquels sont réalisés des prélèvements de tissus et de cellules .</p>  | <p>Ces inspections devront avoir lieu tous les 2 ans.</p>   |

## V. Advertising

|   | <b>Situation before the implementation of Directive 2004/23</b>   | <b>Situation after the implementation of Directive 2004/23</b>                                |
|---|---|---|
| <b>Do you have regulation providing for 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?</b><br>(please tick the appropriate box) | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/><br>Art. L.1211-3. - Est interdite la publicité en faveur d'un don d'éléments ou de produits du corps humain au profit d'une personne déterminée ou au profit d'un établissement ou organisme déterminé. | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/><br>Disposition maintenue  |
| <b>Type of regulation</b> (please tick the appropriate box)   | L <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/>   | L <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> |
| <i>If this regulation is different from the one mentioned under question I, please indicate the title, date and date of entry into force of the regulation</i>  |   |   |
| <b>Describe the prohibitions</b>  | Voir article législatif L.1211-3 mentionné ci-dessus  |   |
| <b>Describe the restrictions</b>  |   |   |

## VI. Additional comments

If you have any additional comments or information please fill out the box below:

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## I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>                                 | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>              |
|--|---|---|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | <input checked="" type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N | <input checked="" type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  | Bioethical laws 94-654 and 2004-800   | Bioethical laws 94-654 and 2004-800   |
| <b>3. Date of the regulation</b>   | 29/07/1994 and  | 29/07/1994 and  |

|  |                        |                        |
|--|------------------------|------------------------|
| (dd/mm/yyyy)   | 06/08/2004             | 06/08/2004             |
| <b>4. Entry into force of the regulation</b><br>(dd/mm/yyyy) | Date of the regulation | Date of the regulation |

## II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|   | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>                               | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>            |
|---|---|---|
| <b>1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?</b>   | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   |
| <b>2. Where are the conditions defined under which compensation may be granted</b>  | L <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/>        | L <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/>        |
| <i>If this regulation is different from the one mentioned under question 1, please indicate its title, date and date of entry into force</i>  | Decree 2000-409 of the 11/05/2000   | Decree 2000-409 of the 11/05/2000   |
| <b>3. What does this compensation entail?</b> (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |   |   |
| a. Expense allowance (please specify the type of expenses covered)  | <i>Clinical examinations, biological exams ,hospitalizations, travels</i>   | <i>Clinical examinations, biological exams ,hospitalizations, travels</i>   |
| b. Time off work (please indicate duration)   | <i>According to the medical need : two to six weeks for kidney donation, few days for hematopoietic stem cell(HSC) donation</i> | <i>According to the medical need : two to six weeks for kidney donation, few days for hematopoietic stem cell(HSC) donation</i> |
| c. Compensation for discomfort endured (please specify)   | <i>No</i>   | <i>No</i>   |
| d. Refreshments (please specify)  | <i>?</i>  | <i>?</i>  |
| e. Others (please specify)  | <i>Accommodation of potential person who go with the donor (parents for HSC minor donor)</i>                                    | <i>Accommodation of potential person who go with the donor (parents for HSC minor donor)</i>                                    |
| f. If there are specific rules for certain types of tissues/cells, please specify   | <i>No</i>   | <i>No</i>   |
| <b>4. Are you aware of cases in your country where donors were</b>  | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/><br>If you answered yes, please specify:                     |   |

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| <b>given remuneration for the donation of tissues and cells?</b> |  |
|--|--|

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>                       |
|---|---|---|
| <b>1. Have measures been taken to <u>promote donation of tissues and cells</u></b><br>(please tick the appropriate box)                 | YES <input type="checkbox"/> NO <input type="checkbox"/>  | YES <input type="checkbox"/> NO <input type="checkbox"/>                                    |
| <b>2. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, donor days, ...) | Information campaigns from Agence de la biomedicine<br>Local information campaigns from volunteer associations<br>National Donor day (22 <sup>nd</sup> of June) |   |
| <b>3. Have measures been taken to <u>endeavour to ensure unpaid donation?</u></b>   | YES <input type="checkbox"/> NO <input type="checkbox"/>  | YES <input type="checkbox"/> NO <input type="checkbox"/>                                    |
| <b>4. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, ...)             | During promotional donation campaign the principles of gratuity of donation are highlighted   | During promotional donation campaign the principles of gratuity of donation are highlighted |

### IV. Promotion of the non-profit procurement of tissues and cells

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|  | <b>Situation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation <u>after</u> the implementation of Directive 2004/23</b> |
|--|--|---|
| <b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br>(please tick the appropriate box) | YES <input type="checkbox"/> NO <input type="checkbox"/>               | YES <input type="checkbox"/> NO <input type="checkbox"/>              |

|   |  |  |
|---|--|--|
| <b>2. Please describe the type of measures taken and the parties involved in their implementation</b> | According to the law (2004/800) the donor has to give his consent in front of an experts committee. One of its attribution is to ensure that nobody put pressure on the potential donor and he carries out his donation on a non-profit basis. | According to the law (2004/800) the donor has to give his consent in front of an experts committee. One of its attribution is to ensure that nobody put pressure on the potential donor and he carries out his donation on a non-profit basis. |
|---|--|--|

### V. Advertising

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>   |
|---|---|---|
| <b>Do you have regulation providing for 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?</b><br>(please tick the appropriate box) | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   |
| <b>Type of regulation</b> (please tick the appropriate box)   | L <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/>                 | L <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/>                 |
| <i>If this regulation is different from the one mentioned under question I, please indicate the title, date and date of entry into force of the regulation</i>  |   |   |
| <b>Describe the prohibitions</b>  | Advertising for donation is prohibited, but this is not an interdiction to information in favour of donation. | Advertising for donation is prohibited, but this is not an interdiction to information in favour of donation. |
| <b>Describe the restrictions</b>  |   |   |

### VI. Additional comments

If you have any additional comments or information please fill out the box below:

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# HUNGARY

## I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>   | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>  |
|--|---|---|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | + L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N   | + L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N   |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  | Act CLIV of 1997 on Health<br>Decree 18/1998 of the Minister of Health on the implementation of the provisions of Act CLIV of 1997 on Health in respect of the transplantation and storing of tissues and organs and certain histopathological examinations | Act CLIV of 1997 on Health<br>Draft decree of the Minister of Health on the modification of Decree 18/1998 of the Minister of Health on the implementation of the provisions of Act CLIV of 1997 on Health in respect of the transplantation and storing of tissues and organs and certain histopathological examinations |
| <b>3. Date of the regulation</b><br>(dd/mm/yyyy)   | 23 December, 1997<br>27 December, 1998  |   |
| <b>4. Entry into force of the regulation</b><br>(dd/mm/yyyy)   | 1 July, 1998<br>1 January, 1999   | Expected in May, 2006   |

## II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|   | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b> |
|---|---|--|
| <b>1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?</b> | YES +                      NO <input type="checkbox"/>  | YES +                      NO <input type="checkbox"/>   |
| <b>2. Where are the conditions defined under which compensation may be granted</b>                | L +   G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/>          | L +   G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/>                             |
| <i>If this regulation is different</i>  |   |  |

|   |  |  |
|---|--|--|
| <i>from the one mentioned under question 1, please indicate its title, date and date of entry into force</i>  |  |  |
| <b>3. What does this compensation entail?</b> (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |  |  |
| a. Expense allowance (please specify the type of expenses covered)  | Act CLIV of 1997 on Health Subsection (1) of Section 207: <i>Donation of organs and tissues shall only take place without consideration given in return.</i><br><br>Subsection (2): <i>The donors shall be eligible for compensation of loss of income related to the donation, and of justified costs incurred in connection with making the statement of donation and with travelling, which are not reimbursed under social insurance coverage. Such costs shall be borne by the state.</i>                                 | The regulation which covers the content of the questionnaire has not changed with the implementation of Directive 2004/23. |
| b. Time off work (please indicate duration)   | <i>Not regulated.</i>  |  |
| c. Compensation for discomfort endured (please specify)   | <i>Not regulated.</i>  |  |
| d. Refreshments (please specify)  | <i>Not regulated.</i>  |  |
| e. Others (please specify)  | <i>Not regulated.</i>  |  |
| f. If there are specific rules for certain types of tissues/cells, please specify   | Donation of reproductive cells: Decree 30/1998 of the Minister of Welfare on the detailed rules concerning the special procedures of human reproduction and the disposal over and the frozen storage of reproductive cells and embryos<br><br>Subsection (2) of Section 3: <i>The donors shall be compensated for the justified and certified costs incurred in the course of the donation in connection with the loss of income, the making the statement of the donation and with travelling not reimbursed under social</i> |  |

|  |   |  |
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|  | <p><i>insurance coverage. Such costs shall be borne subsequently by the health care service provider. Based on the decision of the leader of the health care service provider, the costs may be reimbursed as lump sums.</i></p> <p>Subsection (3): The justified and certified costs shall be reimbursed even if the donation – not through the fault of the donor – does not bring any success.</p> |  |
| <p><b>4. Are you aware of cases in your country where donors were given <u>remuneration</u> for the donation of tissues and cells?</b></p> | <p>YES <input type="checkbox"/> NO <input type="checkbox"/></p> <p>If you answered yes, please specify:</p>   |  |

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>   |
|---|---|---|
| <p><b>1. Have measures been taken to <u>promote</u> donation of tissues and cells</b><br/>(please tick the appropriate box)</p>             | <p>YES <input type="checkbox"/> NO <input type="checkbox"/></p>   | <p>YES <input type="checkbox"/> NO <input type="checkbox"/></p>   |
| <p><b>2. Please describe the type of measures taken</b> (e.g. awareness raising or information campaigns, advertising, donor days, ...)</p> | <p>1. Organisation of ‘Donor Days’ (for donors of bone marrow)</p> <p>2. Charity programme on 19 October, 2005 organised by the Saint Laszlo Stem Cell Foundation with the purpose of improving the hospital conditions of children receiving bone marrow transplantation and raising money for the construction of the ‘Demeter House’ where children could recover under parental supervision after leaving the sterile box following a bone marrow transplantation.</p> <p><u>Round table discussions:</u></p> | <p>The regulation which covers the content of the questionnaire has not changed with the implementation of Directive 2004/23.</p> |

|  |  |  |
|--|--|--|
|  | <p>Popularising the donation of bone marrow<br/> Enlargement of the Hungarian bone marrow donor bank and highlighting the importance of social alliance<br/> 3. Organisation of donor meetings</p>   |  |
| <b>3. Have measures been taken to <u>endeavour to ensure unpaid donation</u>?</b>  | YES +                      NO <input type="checkbox"/>   | YES <input type="checkbox"/> NO <input type="checkbox"/> |
| <b>4. Please describe the type of measures taken (e.g. awareness raising or information campaigns, advertising, ...)</b> | <p>Hungary has acceded to the international campaign on the celebration of 10 millionth voluntary stem cell donation. We plan to celebrate this day every year.<br/> Celebration of the International blood donation day on 14 June.<br/> International workshop organised by the Hungarian Bone Marrow Donation register.</p> |  |

#### IV. Promotion of the non-profit procurement of tissues and cells

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|  | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>   | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>   |
|--|--|---|
| <b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br>(please tick the appropriate box) | YES +                      NO <input type="checkbox"/>   | YES <input type="checkbox"/> NO <input type="checkbox"/>  |
| <b>2. Please describe the type of measures taken and the parties involved in their implementation</b>  | <p>Tissue banks receive fix funding.<br/> Subsection (1)-(4) of Section 14 of Decree 18/1998 of the Minister of Health:<br/> <i>(1) The health care providers listed under Section A) of Annex 6 shall be entitled to implant tissues.</i><br/> <i>(2) The health care providers</i></p> | <p>The regulation which covers the content of the questionnaire has not changed with the implementation of Directive 2004/23.</p> |

|  |   |  |
|--|---|--|
|  | <p><i>listed under Section A) of Annex 6 shall be entitled to remove tissues from a living person with the purpose of transplantation.</i></p> <p><i>(3) The removal of tissues from a dead body with the purpose of transplantation and the storage of these tissues until their processing shall take place at the pathology department of the health care provider or in tissue banks.</i></p> <p><i>(4) The processing of tissues removed from a dead body with the purpose of transplantation and the storage of these tissues after processing shall take place exclusively in tissue banks.</i></p> <p><i>(5) In the cases set forth under Subsection (1)-(4) the health care provider shall meet the personal and material requirements specified in a separate piece of legislation.</i></p> |  |
|--|---|--|

#### V. Advertising

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>                                       | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>                                   |
|---|--|---|
| <b>Do you have regulation providing for 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?</b><br>(please tick the appropriate box) | YES +                      NO <input type="checkbox"/>   | YES <input type="checkbox"/> NO <input type="checkbox"/>  |
| <b>Type of regulation</b> (please tick the appropriate box)   | L +      G <input type="checkbox"/> GNO <input type="checkbox"/>   | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/>                      |
| <i>If this regulation is different from the one mentioned under question I, please indicate the title, date and date of entry into force of the regulation</i>  | Act 6/2002 on the proclamation of the Convention for the protection of Human Rights and dignity of the human | The regulation which covers the content of the questionnaire has not changed with the implementation of |

|                                  |  |                    |
|----------------------------------|--|--------------------|
|                                  | being with regard to the application of biology and medicine : Convention of the Council of Europe on Human Rights and Biomedicine (04/04/1997)  | Directive 2004/23. |
| <b>Describe the prohibitions</b> | <p><u>Act CLIV of 1997 on Health</u><br/> Subsection (2) of Section 203: <i>No advertising of human organs and tissues for any use whatsoever shall be permitted.</i></p> <p>Subsection (1) of Section 207: <i>Donation of organs and tissues shall only take place without consideration given in return.</i></p> <p><u>Article 21 of the Convention on Human Rights and Biomedicine:</u><br/> <i>The human body and its parts shall not, as such, give rise to financial gain.</i></p> |                    |
| <b>Describe the restrictions</b> | <p><u>Act CLIV of 1997 on Health</u><br/> Subsection (1) of Section 203: <i>Primarily organs and tissues removed from cadaver donors should be used for transplantation.</i></p>   |                    |

**VI. Additional comments**

If you have any additional comments or information please fill out the box below:

# IRELAND

## I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>                                 | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>              |
|--|---|---|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | <input type="checkbox"/> L<br><input checked="" type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N | <input type="checkbox"/> L<br><input checked="" type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  | S.I. No 158 of 2006   |   |
| <b>3. Date of the regulation</b><br>(dd/mm/yyyy)   | 7/4/2006  |   |
| <b>4. Entry into force of the regulation</b><br>(dd/mm/yyyy)   | 7/4/2006  |   |

## II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|   | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>                        | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>     |
|---|--|--|
| <b>1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?</b>   | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>  | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>  |
| <b>2. Where are the conditions defined under which compensation may be granted</b>  | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input checked="" type="checkbox"/> | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input checked="" type="checkbox"/> |
| <i>If this regulation is different from the one mentioned under question 1, please indicate its title, date and date of entry into force</i>  |  |  |
| <b>3. What does this compensation entail?</b> (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |  |  |
| a. Expense allowance<br>(please specify the type of expenses covered)   | Travel and Subsistence   | Travel and Subsistence   |
| b. Time off work<br>(please indicate duration)  |  |  |

|   |   |                   |
|---|---|-------------------|
| c. Compensation for discomfort endured (please specify)   |   |                   |
| d. Refreshments (please specify)  | Food and Beverage   | Food and Beverage |
| e. Others (please specify)  |   |                   |
| f. If there are specific rules for certain types of tissues/cells, please specify   |   |                   |
| <b>4. Are you aware of cases in your country where donors were given <u>remuneration</u> for the donation of tissues and cells?</b> | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/><br><br>If you answered yes, please specify: |                   |

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation <u>after</u> the implementation of Directive 2004/23</b> |
|---|--|---|
| <b>1. Have measures been taken to <u>promote donation</u> of tissues and cells</b><br>(please tick the appropriate box)                 | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>    | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>   |
| <b>2. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, donor days, ...) |  |   |
| <b>3. Have measures been taken to <u>endeavour to ensure unpaid donation</u>?</b>   | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>    | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>   |
| <b>4. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, ...)             |  |   |

#### IV. Promotion of the non-profit procurement of tissues and cells

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|  | <b>Situation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation <u>after</u> the implementation of Directive 2004/23</b> |
|--|--|---|
| <b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br>(please tick the appropriate box) | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>    | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>   |
| <b>2. Please describe the type of measures taken and the parties involved in their implementation</b>  |  |   |

#### V. Advertising

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>             | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>              |
|---|--|--|
| <b>Do you have regulation providing for 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?</b><br>(please tick the appropriate box) | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>                | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>                |
| <b>Type of regulation</b> (please tick the appropriate box)   | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> |
| <i>If this regulation is different from the one mentioned under question I, please indicate the title, date and date of entry into force of the regulation</i>  |  |  |
| <b>Describe the prohibitions</b>  |  |  |
| <b>Describe the restrictions</b>  |  |  |

#### VI. Additional comments

If you have any additional comments or information please fill out the box below:

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# ITALY

## I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>                        | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>     |
|--|--|--|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | X <input type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N | X <input type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  | Law 91/1999<br>“Dispositions on organs and tissues retrieval”<br>Law 107/1990<br>Law 52/2001                             | Law 19/2005<br>Draft of Law for application of Directive 23/2004   |
| <b>3. Date of the regulation</b><br>(dd/mm/yyyy)   | 01/04/1999<br>04/05/1990<br>6/3/2001   | 21/10/2005<br>N.A.   |
| <b>4. Entry into force of the regulation</b><br>(dd/mm/yyyy)   | 16/04/1999<br>4/5/1990<br>6/3/2001   | 27/10/2005<br>Probably December 2006   |

## II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|   | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>   |
|---|--|--|
| <b>1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?</b>   | YES <input checked="" type="checkbox"/> X NO <input type="checkbox"/><br>Only for bone marrow donation, not for other kind of tissue or cells donations                                | YES <input type="checkbox"/> X NO <input type="checkbox"/>   |
| <b>2. Where are the conditions defined under which compensation may be granted</b>  | L <input type="checkbox"/> G <input checked="" type="checkbox"/> X GNO <input type="checkbox"/> N<br><input type="checkbox"/><br>IBMDR Manual of Operation, and IBMDR schedule of fees | L <input type="checkbox"/> G <input checked="" type="checkbox"/> X GNO <input type="checkbox"/> N<br><input type="checkbox"/><br>IBMDR Manual of Operation, and IBMDR schedule of fees |
| <i>If this regulation is different from the one mentioned under question I, please indicate its title, date and date of entry into force</i>  |  |  |
| <b>3. What does this compensation entail?</b> (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |  |  |
| a. Expense allowance<br>(please specify the type of expenses covered)   | <i>According to IBMDR Manual of operation only out of pocket expense and if certified (i.e. railway ticket to reach DC/CC)</i>   | <i>According to IBMDR Manual of operation only out of pocket expense and if certified (i.e. railway ticket to reach DC/CC)</i>   |

|   |   |   |
|---|---|---|
|   |   |   |
| b. Time off work<br>(please indicate duration)  | <i>According to our National Law 52, 6 March 2001 entry into force the day after its publication on Gazzetta Ufficiale (official Journal of Italian Government)</i> | <i>According to our National Law 52, 6 March 2001 entry into force the day after its publication on Gazzetta Ufficiale (official Journal of Italian Government)</i> |
| c. Compensation for discomfort endured<br>(please specify)  | <i>NO</i>   | <i>NO</i>   |
| d. Refreshments<br>(please specify)   | <i>NO</i>   | <i>NO</i>   |
| e. Others (please specify)  | <i>N.A.</i>   | <i>N.A.</i>   |
| f. If there are specific rules for certain types of tissues/cells, please specify   | <i>No</i>   | <i>NO</i>   |
| <b>4. Are you aware of cases in your country where donors were given <u>remuneration</u> for the donation of tissues and cells?</b> | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/><br><br>If you answered yes, please specify:   |   |

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation <u>after</u> the implementation of Directive 2004/23</b> |
|---|--|---|
| <b>1. Have measures been taken to <u>promote donation</u> of tissues and cells</b><br>(please tick the appropriate box)                 | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>    | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   |
| <b>2. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, donor days, ...) | Information campaigns<br>Donor week                                    | Information campaigns<br>Donor week                                   |
| <b>3. Have measures been taken to <u>endeavour to ensure unpaid donation</u>?</b>   | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>    | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   |
| <b>4. Please describe the type of measures taken</b>  | On all IBMDR forms and on Law 52 and in any campaign                   | On all IBMDR forms and on Law 52 and in any campaign                  |

|   |   |   |
|---|---|---|
| (e.g. awareness raising or information campaigns, advertising, ...) | is written that stem cell donation is voluntary, anonymous and unpaid | is written that stem cell donation is voluntary, anonymous and unpaid |
|---|---|---|

#### IV. Promotion of the non-profit procurement of tissues and cells

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|  | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>                         | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>                          |
|--|--|--|
| <b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br>(please tick the appropriate box) | YES <input type="checkbox"/> X <input checked="" type="checkbox"/> NO <input type="checkbox"/> | YES <input type="checkbox"/> X <input checked="" type="checkbox"/> NO <input type="checkbox"/> |
| <b>2. Please describe the type of measures taken and the parties involved in their implementation</b>  | Law 91/1999 states that tissues retrieval for profit making is forbidden                       |  |

#### V. Advertising

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>   | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>  |
|---|--|--|
| <b>Do you have regulation providing for 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?</b><br>(please tick the appropriate box) | YES <input type="checkbox"/> X <input checked="" type="checkbox"/> NO <input type="checkbox"/>                           | YES <input type="checkbox"/> X <input checked="" type="checkbox"/> NO <input type="checkbox"/>                           |
| <b>Type of regulation</b> (please tick the appropriate box)   | L <input type="checkbox"/> X <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> | L <input type="checkbox"/> X <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> |
| <i>If this regulation is different from the one mentioned under question I, please indicate the title, date and date of entry into force of the regulation</i>  |  | Draft of law for application of Directive 23/2004, coming into force probably in December 2006                           |
| <b>Describe the prohibitions</b>  | Tissue retrieval for profit making is forbidden  | Not detailed   |

|                                  |  |  |
|----------------------------------|--|--|
| <b>Describe the restrictions</b> |  |  |
|----------------------------------|--|--|

#### VI. Additional comments

If you have any additional comments or information please fill out the box below:

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# LITHUANIA

## I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>              |
|--|--|---|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | <input checked="" type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N  | <input checked="" type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  | Law on the Amendment on Human Tissues, Cells and Organs Donation and Transplantation   | Law on the Amendment on Human Tissues, Cells and Organs Donation and Transplantation  |
| <b>3. Date of the regulation</b><br>(dd/mm/yyyy)   | Voluntary and unpaid donation of tissues was regulated since 11/19/1996<br>The Amendment that also includes voluntary and unpaid donation of cells was adopted at 25/03/2004 |   |
| <b>4. Entry into force of the regulation</b><br>(dd/mm/yyyy)   | Voluntary and unpaid donation of tissues – 11/19/1996<br>Voluntary and unpaid donation of cells – 25/03/2004   |   |

## II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|   | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>             | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b> |
|---|---|--|
| <b>1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?</b>   | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>   | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>  |
| <b>2. Where are the conditions defined under which compensation may be granted</b>                  | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/> | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/>        |
| <i>If this regulation is different from the one mentioned under question I, please indicate its</i> |   |  |

|   |   |  |
|---|---|--|
| <i>title, date and date of entry into force</i>   |   |  |
| <b>3. What does this compensation entail?</b> (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |   |  |
| a. Expense allowance<br>(please specify the type of expenses covered)   |   |  |
| b. Time off work<br>(please indicate duration)  |   |  |
| c. Compensation for discomfort endured<br>(please specify)  |   |  |
| d. Refreshments<br>(please specify)   |   |  |
| e. Others (please specify)  |   |  |
| f. If there are specific rules for certain types of tissues/cells, please specify   |   |  |
| <b>4. Are you aware of cases in your country where donors were given <u>remuneration</u> for the donation of tissues and cells?</b>   | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/><br><br>If you answered yes, please specify: |  |

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>  |
|---|---|--|
| <b>1. Have measures been taken to <u>promote donation</u> of tissues and cells</b><br>(please tick the appropriate box)                 | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>  |
| <b>2. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, donor days, ...) | Information campaigns:<br>“Get Donor card”<br>“Be an Organ Donor”<br>Advertising posts<br>Organ donor day<br>TV and radio shows<br>Lectures for student | Information campaigns:<br>“Get Donor card”<br>“Be an Organ Donor”<br>Advertising posts<br>Organ donor day<br>TV and radio shows<br>Lectures for students |
| <b>3. Have measures been taken to <u>endeavour to ensure unpaid donation</u>?</b>   | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>  |

|  |   |   |
|--|---|---|
| <b>4. Please describe the type of measures taken</b> (e.g. awareness raising or information campaigns, advertising, ...) | All measures described in article 2 we oriented also to promote unpaid and volunteered donation | All measures described in article 2 we oriented also to promote unpaid and volunteered donation |
|--|---|---|

**IV. Promotion of the non-profit procurement of tissues and cells**

This concerns measures taken in order to endeavour to ensure that procurement organizations and procurement teams work on a non-profit basis.

|  | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>   |
|--|---|---|
| <b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br>(please tick the appropriate box) | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   |
| <b>2. Please describe the type of measures taken and the parties involved in their implementation</b>  | Article 10 of Law on the Amendment on Human Tissues, Cells and Organs Donation and Transplantation says that tissues, cells and organs of a dead or living person cannot be the subject of civil commercial transactions. | Article 10 of Law on the Amendment on Human Tissues, Cells and Organs Donation and Transplantation says that tissues, cells and organs of a dead or living person cannot be the subject of civil commercial transactions. |

**V. Advertising**

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>                        | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>                         |
|---|---|---|
| <b>Do you have regulation providing for 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?</b><br>(please tick the appropriate box) | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>                           | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>                           |
| <b>Type of regulation</b> (please tick the appropriate box)   | L <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> | L <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> |
| <i>If this regulation is different from</i>   |   |   |

|   |   |   |
|---|---|---|
| <i>the one mentioned under question I, please indicate the title, date and date of entry into force of the regulation</i> |   |   |
| <b>Describe the prohibitions</b>  | Article 10 of Law on the Amendment on Human Tissues, Cells and Organs Donation and Transplantation says that tissues, cells and organs of a dead or living person cannot be the subject of civil commercial transactions. | Article 10 of Law on the Amendment on Human Tissues, Cells and Organs Donation and Transplantation says that tissues, cells and organs of a dead or living person cannot be the subject of civil commercial transactions. |
| <b>Describe the restrictions</b>  |   |   |

**VI. Additional comments**

If you have any additional comments or information please fill out the box below:

# LUXEMBOURG

## I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | Situation in the national regulation <u>before</u> the implementation of Directive 2004/23  | Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23   |
|--|---|---|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | L   | L   |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  | Loi du 25 novembre 1982 réglant le prélèvement de substances d'origine humaine.<br><br><i>Law of the 25th November 1982 regulating the taking of substances of human origin</i> | Projet<br>Loi relative aux tissus et cellules humains utilisés à des fins thérapeutiques et scientifiques<br><i>Draft Law relating to human tissues and cells used for therapeutic and scientific goals</i> |
| <b>3. Date of the regulation</b><br>(dd/mm/yyyy)   | 25/11/1982  | ?   |
| <b>4. Entry into force of the regulation</b><br>(dd/mm/yyyy)   | 06/12/1982  | ?   |

## II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|  | Situation in the national regulation <u>before</u> the implementation of Directive 2004/23 | Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23 |
|--|--|---|
| <b>1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?</b>  | Yes  | Yes   |
| <b>2. Where are the conditions defined under which compensation may be granted</b>   | L  | L   |
| <i>If this regulation is different from the one mentioned under question I, please indicate its title, date and date of entry into force</i> |  |   |

|   |  |                       |
|---|--|-----------------------|
| <b>3. What does this compensation entail?</b> (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |  |                       |
| a. Expense allowance<br>(please specify the type of expenses covered)   | <i>Loss of income</i>                          | <i>Loss of income</i> |
| b. Time off work<br>(please indicate duration)  | <i>Loss of income</i>                          | <i>Loss of income</i> |
| c. Compensation for discomfort endured<br>(please specify)  | <i>no</i>                                      | <i>no</i>             |
| d. Refreshments<br>(please specify)   |  |                       |
| e. Others (please specify)  |  |                       |
| f. If there are specific rules for certain types of tissues/cells, please specify   |  |                       |
| <b>4. Are you aware of cases in your country where donors were given remuneration for the donation of tissues and cells?</b>  | NO<br><br>If you answered yes, please specify: |                       |

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation <u>after</u> the implementation of Directive 2004/23</b> |
|---|--|---|
| <b>1. Have measures been taken to <u>promote</u> donation of tissues and cells</b><br>(please tick the appropriate box)                 | NO   | ?   |
| <b>2. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, donor days, ...) |  |   |
| <b>3. Have measures been taken to <u>endeavour to ensure unpaid</u> donation?</b>   | NO   | ?   |
| <b>4. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, ...)             |  |   |

#### IV. Promotion of the non-profit procurement of tissues and cells

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|  | <b>Situation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation <u>after</u> the implementation of Directive 2004/23</b> |
|--|--|---|
| <b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br>(please tick the appropriate box) | NO   | ?   |
| <b>2. Please describe the type of measures taken and the parties involved in their implementation</b>  |  |   |

#### V. Advertising

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation <u>after</u> the implementation of Directive 2004/23</b> |
|---|--|---|
| <b>Do you have regulation providing for 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?</b><br>(please tick the appropriate box) | Yes  | Yes   |
| <b>Type of regulation</b> (please tick the appropriate box)   | L  | L   |
| <i>If this regulation is different from the one mentioned under question I, please indicate the title, date and date of entry into force of the regulation</i>  |  |   |
| <b>Describe the prohibitions</b>  | Donation is free   | Donation is free  |
| <b>Describe the restrictions</b>  | Donation is free   | Donation is free  |

#### VI. Additional comments

If you have any additional comments or information please fill out the box below:

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# LATVIA

### I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>                                 | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>              |
|--|---|---|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | <input checked="" type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N | <input checked="" type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  | Law on Protection of Deceased Human's Body and Application of Human's Tissues and Organs in the Medicine                          | Law on Protection of Deceased Human's Body and Application of Human's Tissues and Organs in the Medicine                          |
| <b>3. Date of the regulation</b><br>(dd/mm/yyyy)   | 15/12/1992  | 15/12/1992  |
| <b>4. Entry into force of the regulation</b><br>(dd/mm/yyyy)   | 01/01/1993  | 01/01/1993  |

### II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|   | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>                                 | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>              |
|---|---|---|
| <b>1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?</b>   | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>   | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>   |
| <b>2. Where are the conditions defined under which compensation may be granted</b>  | <input type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input checked="" type="checkbox"/> N | <input type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input checked="" type="checkbox"/> N |
| <i>If this regulation is different from the one mentioned under question I, please indicate its title, date and date of entry into force</i>  |   |   |
| <b>3. What does this compensation entail?</b> (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |   |   |

|   |   |  |
|---|---|--|
| a. Expense allowance<br>(please specify the type of expenses covered)   |   |  |
| b. Time off work<br>(please indicate duration)  |   |  |
| c. Compensation for discomfort endured<br>(please specify)  |   |  |
| d. Refreshments<br>(please specify)   |   |  |
| e. Others (please specify)  |   |  |
| f. If there are specific rules for certain types of tissues/cells, please specify   |   |  |
| <b>4. Are you aware of cases in your country where donors were given <u>remuneration</u> for the donation of tissues and cells?</b> | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/><br>If you answered yes, please specify: |  |

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation <u>after</u> the implementation of Directive 2004/23</b> |
|---|--|---|
| <b>1. Have measures been taken to <u>promote donation</u> of tissues and cells</b><br>(please tick the appropriate box)                 | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>    | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>   |
| <b>2. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, donor days, ...) |  |   |
| <b>3. Have measures been taken to <u>endeavour to ensure unpaid donation</u>?</b>   | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>    | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>   |
| <b>4. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, ...)             |  |   |

#### IV. Promotion of the non-profit procurement of tissues and cells

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|  | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>   |
|--|---|---|
| <b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br>(please tick the appropriate box) | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   |
| <b>2. Please describe the type of measures taken and the parties involved in their implementation</b>  | Pursuant to Law on Protection of Deceased Human's Body and Application of Human's Tissues and Organs in the Medicine, procuring and application of tissues or organs from a living person or deceased person use for a purpose of development of medicine, and it's carried out on a non-profit basis. Procuring of tissues or organs from living person or deceased person is authorized strictly, after the person concerned has given consent or disapproval, and the selection, transmission and application of the tissues or organs as a purpose of commercial transaction is prohibited. | Pursuant to Law on Protection of Deceased Human's Body and Application of Human's Tissues and Organs in the Medicine, procuring and application of tissues or organs from a living person or deceased person use for a purpose of development of medicine, and it's carried out on a non-profit basis. Procuring of tissues or organs from living person or deceased person is authorized strictly, after the person concerned has given consent or disapproval, and the selection, transmission and application of the tissues or organs as a purpose of commercial transaction is prohibited. |

#### V. Advertising

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation <u>after</u> the implementation of Directive 2004/23</b> |
|---|--|---|
| <b>Do you have regulation providing for 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</b> | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>    | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>   |

|  |  |  |
|--|--|--|
| <b>comparable advantages?</b><br>(please tick the appropriate box)   |  |  |
| <b>Type of regulation</b> (please tick the appropriate box)  | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> |
| <i>If this regulation is different from the one mentioned under question I, please indicate the title, date and date of entry into force of the regulation</i> |  |  |
| <b>Describe the prohibitions</b>   |  |  |
| <b>Describe the restrictions</b>   |  |  |

**VI. Additional comments**

If you have any additional comments or information please fill out the box below:

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# MALTA

## I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>                             | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>          |
|--|---|---|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | <input type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> <u>N</u> | <input type="checkbox"/> <u>L</u><br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  |   | The Human Blood and Transplants Act 2006  |
| <b>3. Date of the regulation</b><br>(dd/mm/yyyy)   |   | 11/04/2006  |
| <b>4. Entry into force of the regulation</b><br>(dd/mm/yyyy)   |   | 05/2006   |

## II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|   | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>             | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b> |
|---|---|--|
| <b>1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?</b>   | YES <input type="checkbox"/> <u>NO</u> <input type="checkbox"/>   | YES <input type="checkbox"/> <u>NO</u> <input type="checkbox"/>  |
| <b>2. Where are the conditions defined under which compensation may be granted</b>  | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/> | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/>        |
| <i>If this regulation is different from the one mentioned under question 1, please indicate its title, date and date of entry into force</i>  |   |  |
| <b>3. What does this compensation entail?</b> (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |   |  |
| a. Expense allowance<br>(please specify the type of expenses covered)   |   |  |
| b. Time off work<br>(please indicate duration)  |   |  |

|   |  |  |
|---|--|--|
| c. Compensation for discomfort endured (please specify)   |  |  |
| d. Refreshments (please specify)  |  |  |
| e. Others (please specify)  |  |  |
| f. If there are specific rules for certain types of tissues/cells, please specify   |  |  |
| <b>4. Are you aware of cases in your country where donors were given <u>remuneration</u> for the donation of tissues and cells?</b> | YES <input type="checkbox"/> <u><b>NO</b></u> <input type="checkbox"/><br><br>If you answered yes, please specify: |  |

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>  |
|---|--|--|
| <b>1. Have measures been taken to <u>promote donation</u> of tissues and cells</b><br>(please tick the appropriate box)                 | <u><b>YES</b></u> <input type="checkbox"/> NO <input type="checkbox"/> | <u><b>YES</b></u> <input type="checkbox"/> NO <input type="checkbox"/> |
| <b>2. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, donor days, ...) | Awareness Raising and Information Campaigns                            | Awareness Raising and Information Campaigns                            |
| <b>3. Have measures been taken to <u>endeavour to ensure unpaid donation</u>?</b>   | YES <input type="checkbox"/> <u><b>NO</b></u> <input type="checkbox"/> | YES <input type="checkbox"/> <u><b>NO</b></u> <input type="checkbox"/> |
| <b>4. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, ...)             |  |  |

#### IV. Promotion of the non-profit procurement of tissues and cells

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|  | <b>Situation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation <u>after</u> the implementation of Directive 2004/23</b> |
|--|--|---|
| <b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br>(please tick the appropriate box) | YES <input type="checkbox"/> <u>NO</u> <input type="checkbox"/>        | YES <input type="checkbox"/> <u>NO</u> <input type="checkbox"/>       |
| <b>2. Please describe the type of measures taken and the parties involved in their implementation</b>  |  |   |

#### V. Advertising

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>             | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>              |
|---|--|--|
| <b>Do you have regulation providing for 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?</b><br>(please tick the appropriate box) | YES <input type="checkbox"/> <u>NO</u> <input type="checkbox"/>                    | YES <input type="checkbox"/> <u>NO</u> <input type="checkbox"/>                    |
| <b>Type of regulation</b> (please tick the appropriate box)   | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> |
| <i>If this regulation is different from the one mentioned under question 1, please indicate the title, date and date of entry into force of the regulation</i>  |  |  |
| <b>Describe the prohibitions</b>  |  |  |
| <b>Describe the restrictions</b>  |  |  |

## VI. Additional comments

If you have any additional comments or information please fill out the box below:

The Legislative Act on Human Blood and Transplants, which implements Directive 2004/33 has just passed through the Maltese Parliament and has been approved and published. It is foreseen that it will come into force by June 2006.

Malta is currently in the process of drafting Regulations, to be published under the above Act, that will cover restrictions on advertising, as well as measures to ensure that procurement of tissues and cells as such is carried out on a non-profit basis. It is foreseen that these regulations will come into force before 1 November 2006.

# THE NETHERLANDS

## I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b> |
|--|---|--|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | x L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N   | x L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N                      |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  | Wet op de orgaandonatie<br><br>Organ donation Act   | Wet op de orgaandonatie<br><br>Organ donation Act  |
| <b>3. Date of the regulation</b><br>(dd/mm/yyyy)   | 24/05/1996  | Idem   |
| <b>4. Entry into force of the regulation</b><br>(dd/mm/yyyy)   | 01/02/1998  | idem   |

## II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|   | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>             | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b> |
|---|---|--|
| <b>1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?</b>   | YES <input type="checkbox"/> NO x   | YES <input type="checkbox"/> NO x  |
| <b>2. Where are the conditions defined under which compensation may be granted</b><br><i>If this regulation is different from the one mentioned under question 1, please indicate its title, date and date of entry into force</i>          | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/> | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/>        |
| <b>3. What does this compensation entail?</b> (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |   |  |
| a. Expense allowance<br>(please specify the type of expenses covered)   |   |  |
| b. Time off work<br>(please indicate duration)  |   |  |

|   |   |  |
|---|---|--|
| c. Compensation for discomfort endured (please specify)   |   |  |
| d. Refreshments (please specify)  |   |  |
| e. Others (please specify)  |   |  |
| f. If there are specific rules for certain types of tissues/cells, please specify   |   |  |
| <b>4. Are you aware of cases in your country where donors were given <u>remuneration</u> for the donation of tissues and cells?</b> | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/><br><br>If you answered yes, please specify: |  |

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>   | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>    |
|---|--|--|
| <b>1. Have measures been taken to <u>promote donation</u> of tissues and cells</b><br>(please tick the appropriate box)                 | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>      | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>      |
| <b>2. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, donor days, ...) | awareness raising or information campaigns, advertising, donor days etc. | awareness raising or information campaigns, advertising, donor days etc. |
| <b>3. Have measures been taken to <u>endeavour to ensure unpaid donation</u>?</b>   | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>      | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>      |
| <b>4. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, ...)             | awareness raising or information campaigns, advertising etc              | awareness raising or information campaigns, advertising etc              |

#### IV. Promotion of the non-profit procurement of tissues and cells

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|  | <b>Situation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation <u>after</u> the implementation of Directive 2004/23</b> |
|--|--|---|
| <b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br>(please tick the appropriate box) | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>    | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>   |
| <b>2. Please describe the type of measures taken and the parties involved in their implementation</b>  |  |   |

#### V. Advertising

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>                          | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>                           |
|---|---|---|
| <b>Do you have regulation providing for 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?</b><br>(please tick the appropriate box) | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>                             | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>                             |
| <b>Type of regulation</b> (please tick the appropriate box)   | L <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/>   | L <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/>   |
| <i>If this regulation is different from the one mentioned under question I, please indicate the title, date and date of entry into force of the regulation</i>  |   |   |
| <b>Describe the prohibitions</b>  | It is forbidden to offer or advertise for tissues and cells in order to receive financial gain. | It is forbidden to offer or advertise for tissues and cells in order to receive financial gain. |
| <b>Describe the restrictions</b>  |   |   |

## VI. Additional comments

If you have any additional comments or information please fill out the box below:

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# POLAND

(two reports received)

## I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | Situation in the national regulation <u>before</u> the implementation of Directive 2004/23      | Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23 |
|--|---|---|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | X L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N | X L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N               |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  | The Act of October 26, 1995 on cell, tissue and organ recovery and transplantation              | The Act of July 1, 2005 on cell, tissue and organ recovery, storage and transplantation                       |
| <b>3. Date of the regulation</b><br>(dd/mm/yyyy)   | 26/10/1995  | 01/07/2005  |
| <b>4. Entry into force of the regulation</b><br>(dd/mm/yyyy)   | 26/01/1996  | 01/01/2006  |

## II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|   | Situation in the national regulation <u>before</u> the implementation of Directive 2004/23                    | Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23 |
|---|---|---|
| <b>1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?</b>   | YES <input type="checkbox"/> NO X   | YES <input type="checkbox"/> NO X   |
| <b>2. Where are the conditions defined under which compensation may be granted</b><br><i>If this regulation is different from the one mentioned under question 1, please indicate its title, date and date of entry into force</i>          | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/> | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/> |
| <b>3. What does this compensation entail?</b> (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |   |   |
| a. Expense allowance<br>(please specify the type of expenses covered)   |   |   |
| b. Time off work<br>(please indicate duration)  |   |   |

|   |   |  |
|---|---|--|
| c. Compensation for discomfort endured (please specify)   |   |  |
| d. Refreshments (please specify)  |   |  |
| e. Others (please specify)  |   |  |
| f. If there are specific rules for certain types of tissues/cells, please specify   |   |  |
| <b>4. Are you aware of cases in your country where donors were given <u>remuneration</u> for the donation of tissues and cells?</b> | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/><br><br>If you answered yes, please specify: |  |

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|  | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>   | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>  |
|--|--|--|
| <b>1. Have measures been taken to <u>promote donation</u> of tissues and cells</b><br>(please tick the appropriate box)              | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>  | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>  |
| <b>2. Please describe the type of measures taken</b> (e.g. awareness raising or information campaigns, advertising, donor days, ...) | Educational activities are performed by the national transplant organization "POLTRANSPLANT" which include: information and advertising campaigns, meetings, lectures, special events etc. Promotion of bone marrow donation with street posters and leaflets. | According to the new Transplantation Law of July 1, 2005, there is a special chapter dedicated for donation of cells, tissues and organs or their parts. It states, that a donor of bone marrow or other regenerating cells and tissues is entitled to use the title of "Transplant Donor". A transplant donor who donated bone marrow or other regenerating cells and tissues more than once and an organ donor are entitled to use the title of "Transplant Donor Worthy". A "Transplant Donor" and "Transplant Donor Worthy" is entitled to use outpatient health care services without appointment. Additionally, performance of educational activities aimed at |

|  |   |   |
|--|---|---|
|  |   | dissemination the treatment with the method of cell, tissue and organ transplantation lies in the competency of the national transplant organization "POLTRANSPLANT". |
| <b>3. Have measures been taken to <u>endeavour to ensure unpaid donation</u>?</b>  | YES X                      NO <input type="checkbox"/>  | YES X                      NO <input type="checkbox"/>  |
| <b>4. Please describe the type of measures taken (e.g. awareness raising or information campaigns, advertising, ...)</b> | During educational activities performed by the national transplant organization "POLTRANSPLANT" this subject has been raised. | During educational activities performed by the national transplant organization "POLTRANSPLANT" this subject has been raised.   |

#### IV. Promotion of the non-profit procurement of tissues and cells

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|  | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>   | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>   |
|--|--|---|
| <b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br>(please tick the appropriate box) | YES X                      NO <input type="checkbox"/>   | YES X                      NO <input type="checkbox"/>  |
| <b>2. Please describe the type of measures taken and the parties involved in their implementation</b>  | Legal measures - Procurement of tissues and cells was carrying out by the institutions authorised by the minister of health on the basis of the fulfilling special requirements (supply, room, properly qualified staff etc.). Organisational measures- national transplant organisation "Poltransplant" was responsible for co-ordination of recovery and | Legal measures – Procurement of tissues and cells is carrying out by the institutions which are authorised by the minister of health on the basis of the fulfilling special requirements (executives – in preparation). Legal and organisational measures - national transplant organisation "Poltransplant" is responsible |

|  |   |   |
|--|---|---|
|  | transplantation of cells, tissues and organs in Poland. | for co-ordination of recovery and transplantation of cells, tissues and organs in Poland. "Poltransplant" is responsible for the above tasks on the basis of new transplantation Law of July 1, 2005. |
|--|---|---|

## V. Advertising

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>   | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>  |
|---|--|--|
| <b>Do you have regulation providing for 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?</b><br>(please tick the appropriate box) | YES X                      NO <input type="checkbox"/>   | YES X                      NO <input type="checkbox"/>   |
| <b>Type of regulation</b> (please tick the appropriate box)   | L X    G <input type="checkbox"/> GNO <input type="checkbox"/>   | L X    G <input type="checkbox"/> GNO <input type="checkbox"/>   |
| <i>If this regulation is different from the one mentioned under question I, please indicate the title, date and date of entry into force of the regulation</i>  |  |  |
| <b>Describe the prohibitions</b>  | <p>1.) All those who disseminate notices about payable sales, purchases of cells, tissues and organs or about an agency for payable sales or purchases of cells, tissues and organs with the aim of transplanting them shall be liable to a fine.</p> <p>2.) All those who with the purpose of acquiring financial benefits buy or sell other people's cells, tissues or organs, run an agency for the purchase and sale of cells, tissues or organs or take part in transplantations of recovered in defiance of the regulations of the present act cells, tissues or organs that originate from living</p> | <p>1.) All those who disseminate notices about payable sales, purchases of cells, tissues and organs or about an agency for payable sales or purchases of cells, tissues and organs with the aim of transplanting them shall be liable to a fine, a penalty of imprisonment.</p> <p>2.) All those who with the purpose of acquiring financial benefits buy or sell other people's cells, tissues or organs, run an agency for the purchase and sale of cells, tissues or organs or take part in transplantations of recovered in defiance of the regulations of the present act cells, tissues or organs</p> |

|   |   |  |
|---|---|--|
|   | <p>donors or human dead bodies, shall be liable to a penalty of imprisonment.</p> <p>3.) All offenders who have a fixed income source through perpetration of the crime stated in paragraph 1 shall be liable to a penalty of imprisonment.</p> | <p>that originate from living donors or human dead bodies, shall be liable to a penalty of imprisonment.</p> <p>3.) All offenders who have a fixed income source through perpetration of the crime stated in point 2, shall be liable to a penalty of imprisonment.</p> <p>4.) All those who perform activities, which the regulations in the Act provide for tissue and cell banks, without having the required permission shall be liable to a fine, a penalty of imprisonment or a penalty of imprisonment.</p> <p>5.) All those who without having the required permission recover cells, tissues or organs for transplantations or transplant these shall be liable to a fine, a penalty of imprisonment.</p> |
| <p><b>Describe the restrictions</b></p> | <p>1.) A fine of 5000 PLN.</p> <p>2.) A penalty of imprisonment of up to three years.</p> <p>3.) A penalty of imprisonment of up to ten years.</p>  | <p>1.) A fine, a penalty of imprisonment or a penalty of imprisonment of up to one year.</p> <p>2.) A penalty of imprisonment of three years or more.</p> <p>3.) A penalty of imprisonment of five years or more.</p> <p>4.) A penalty of imprisonment of up to one year.</p> <p>5.) A penalty of imprisonment or a penalty of imprisonment of up to three years.</p>  |

## VI. Additional comments

If you have any additional comments or information please fill out the box below:

In addition to chapter II. point 1. and 2. concerning the compensation for the donation of tissues or cells, according to new Law on transplantation of July 1, 2005, we explain that:

1. It is not allowed to demand or accept payments or other financial benefit for cells, tissues and organs taken from donors.

2. The repayment of costs of recovery, storage, processing, sterilization, distribution and transplantation of cells, tissues or organs taken from donors is not a payment or financial benefit within the meaning of paragraph 1.

3. The costs of recovery, storage, processing, sterilization, distribution and transplantation of cells, tissues or organs include the costs of: a recovery of cells, tissues or organs from a donor; a hospitalization of a potentially living donor; an issuance of medical opinions; a recovery procedure; laboratory tests performed before and after the recovery; a cell culture for transplantation; a transport from or to the medical care institution where the transplantation has to be done; a storage, processing and sterilization.

4. The repayment of costs referred to in paragraph 3 shall be done by the medical care institution, which has been supplied with cells, tissues or organs for transplantation. The medical care institution, which have performed a transplantation of cells, tissues and organs receive financial means from the minister of health.

A donor of bone marrow or peripheral blood hematopoietic cells and an organ donor, who in consequence of the recovery procedure suffered a body injury or health breakdown, have the right to claim for compensation on the basis of the regulations of the Civil Code.

### I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>  |
|--|--|---|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | <input checked="" type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N  | <input checked="" type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N   |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  | Ustawa z dnia 26 października 1995 r. o pobieraniu i przeszczepianiu komorek, tkanek i narządów.<br><br>(Regulation of 26 October 1995 on procurement and transplantation of cells, tissues and organs). | Ustawa z dnia 1 lipca 2005 r. o pobieraniu, przechowywaniu i przeszczepianiu komorek, tkanek i narządów.<br><br>(Regulation of 1 July 2005 on procurement, storage and transplantation of cells, tissues and organs). |

|  |            |            |
|--|------------|------------|
| <b>3. Date of the regulation</b><br>(dd/mm/yyyy)             | 26/10/1995 | 01/07/2005 |
| <b>4. Entry into force of the regulation</b><br>(dd/mm/yyyy) | 06/03/1996 | 01/01/2006 |

## II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|   | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>                        | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>   |
|---|--|--|
| <b>1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?</b>   | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>  | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>  |
| <b>2. Where are the conditions defined under which compensation may be granted</b>  | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input checked="" type="checkbox"/> | L <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/>   |
| <i>If this regulation is different from the one mentioned under question 1, please indicate its title, date and date of entry into force</i>  |  | As mentioned under question I.   |
| <b>3. What does this compensation entail?</b> (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |  |  |
| a. Expense allowance (please specify the type of expenses covered)  | <i>Non-applicable</i>  | <i>Non-applicable</i>  |
| b. Time off work (please indicate duration)   | <i>Non-applicable</i>  | <i>Non-applicable</i>  |
| c. Compensation for discomfort endured (please specify)   | <i>Non-applicable</i>  | <i>Non-applicable</i>  |
| d. Refreshments (please specify)  | <i>Non-applicable</i>  | <i>Non-applicable</i>  |
| e. Others (please specify)  | <i>Non-applicable</i>  | <i>Non-applicable</i>  |
| f. If there are specific rules for certain types of tissues/cells, please specify   | <i>Non-applicable</i>  | <i>Donors of bone marrow or other regenerating cells or tissues are awarded a title of “Graft Donor” or “Meritorious Graft Donor” (if they gave more than one donation), together with the membership card and the special badge. Moreover, such donors enjoy a privilege of out of turn ambulatory treatment in public health care service.</i> |

|   |   |
|---|---|
| <b>4. Are you aware of cases in your country where donors were given <u>remuneration</u> for the donation of tissues and cells?</b> | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/><br><br>If you answered yes, please specify: |
|---|---|

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>   |
|---|---|---|
| <b>1. Have measures been taken to <u>promote donation of tissues and cells</u></b><br>(please tick the appropriate box)                 | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   |
| <b>2. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, donor days, ...) | <p>Modes of activities undertaken in Poland to promote the voluntary and unpaid donation of tissues and cells:</p> <ul style="list-style-type: none"> <li>- information campaigns in mass-media to raise public awareness of the issue;</li> <li>- presentation of the attitude to the donation of the popular in the society moral authorities and opinion leaders;</li> <li>- moral support from the Roman Catholic Church officials of high range informing that voluntary and unpaid donation of tissues and cells is not in conflict with the foundations of the religion;</li> <li>- annual Transplantology Day and Donor Days establishment;</li> <li>- promotion of the donation by the foundation of associations of organ, tissue and cell recipients and supporting their meetings;</li> <li>- collaboration with physician associations to promote the idea of donation.</li> </ul> | <p>Modes of activities undertaken in Poland to promote the voluntary and unpaid donation of tissues and cells:</p> <ul style="list-style-type: none"> <li>- information campaigns in mass-media to raise public awareness of the issue;</li> <li>- presentation of the attitude to the donation of the popular in the society moral authorities and opinion leaders;</li> <li>- moral support from the Roman Catholic Church officials of high range informing that voluntary and unpaid donation of tissues and cells is not in conflict with the foundations of the religion;</li> <li>- website information on donation principles and advantages of transplantation from institutions engaged in transplantation, such as: the National Centre of Tissue and Cell Banking, the National Transplantation Council, and the Centre for Organization and Coordination of Transplantation Affairs-“POLTRANSPLANT”;</li> <li>- raising of public and</li> </ul> |

|  |   |   |
|--|---|---|
|  |   | <p>medical professionals awareness on advantages associated with transplantation of organs, tissues and cells by organizing training courses, partly financed from the European Union Transition Facility Project;</p> <p>- annual Transplantology Day and Donor Days establishment;</p> <p>- promotion of the donation by the foundation of associations of organ, tissue and cell recipients and supporting their meetings;</p> <p>- collaboration with physician associations to promote the idea of donation.</p> |
| <b>3. Have measures been taken to <u>endeavour to ensure unpaid donation?</u></b>  | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   |
| <b>4. Please describe the type of measures taken (e.g. awareness raising or information campaigns, advertising, ...)</b> | During all modes of promotion activities mentioned above, special emphasis is laid on the raising of public awareness and understanding of the altruistic idea of voluntary and unpaid donation in purpose to rescue health and life of other people. | During all modes of promotion activities mentioned above, special emphasis is laid on the raising of public awareness and understanding of the altruistic idea of voluntary and unpaid donation in purpose to rescue health and life of other people.   |

#### IV. Promotion of the non-profit procurement of tissues and cells

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|  | <b>Situation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation <u>after</u> the implementation of Directive 2004/23</b> |
|--|--|---|
| <b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br>(please tick the appropriate box) | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>    | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   |

|   |  |   |
|---|--|---|
| <b>2. Please describe the type of measures taken and the parties involved in their implementation</b> | Ustawa z dnia 26 października 1995 r. o pobieraniu i przeszczepianiu komorek, tkanek i narządów.<br><br>(Regulation of 26 October 1995 on procurement and transplantation of cells, tissues and organs). | Ustawa z dnia 1 lipca 2005 r. o pobieraniu, przechowywaniu i przeszczepianiu komorek, tkanek i narządów.<br><br>(Regulation of 1 July 2005 on procurement, storage and transplantation of cells, tissues and organs). |
|---|--|---|

## V. Advertising

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>   |
|---|---|---|
| <b>Do you have regulation providing for 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?</b><br>(please tick the appropriate box) | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   |
| <b>Type of regulation</b> (please tick the appropriate box)   | L <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/>   | L <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/>   |
| <i>If this regulation is different from the one mentioned under question I, please indicate the title, date and date of entry into force of the regulation</i>  | As mentioned under question I.  | As mentioned under question I.  |
| <b>Describe the prohibitions</b>  | It is prohibited to demand or to receive remuneration or other financial advantages for cells, tissues and organs procured from living donors or cadaveric donors.  | It is prohibited to demand or to receive remuneration or other financial advantages for cells, tissues and organs procured from living donors or cadaveric donors.  |
| <b>Describe the restrictions</b>  | Anyone who advertises payable selling or buying of cells, tissues and organs to be transplanted (or mediates in such advertising) is liable to the penalty of fine. Payable buying, selling as well as mediation in buying or selling, or taking part in transplantation of human | Anyone who advertises payable selling or buying of cells, tissues and organs to be transplanted (or mediates in such advertising), is liable to penalty of fine, limitation of freedom or imprisonment.<br><br>Payable buying, selling as |

|  |  |   |
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|  | <p>cells, tissues and organs procured from living donors or cadaveric donors with infringement of the law, is liable to the penalty of fine or imprisonment.</p> | <p>well as mediation in buying or selling, or taking part in transplantation of human cells, tissues and organs procured from living donors or cadaveric donors with infringement of the law, is liable to the penalty of imprisonment.</p> <p>Who, without required permission, conducts activities provided by the regulation for Cell and Tissue Bank, is liable to the penalty of fine, limitation of freedom or imprisonment.</p> <p>Who, without required permission, procures cells, tissues and organs in purpose of transplantation, or who transplants them, is liable to the penalty of fine, limitation of freedom or imprisonment.</p> |
|--|--|---|

**VI. Additional comments**

If you have any additional comments or information please fill out the box below:

# PORTUGAL

## I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | Situation in the national regulation <u>before</u> the implementation of Directive 2004/23             | Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23 |
|--|--|---|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | <b>X</b> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N | <b>X</b> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N        |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  | See enclosed Law 12/93   |   |
| <b>3. Date of the regulation</b><br>(dd/mm/yyyy)   | 22/04/1993   |   |
| <b>4. Entry into force of the regulation</b><br>(dd/mm/yyyy)   | 27/09/1993   |   |

## II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|   | Situation in the national regulation <u>before</u> the implementation of Directive 2004/23       | Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23 |
|---|--|---|
| <b>1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?</b>   | YES <input type="checkbox"/> NO <b>X</b>   | YES <input type="checkbox"/> NO <b>X</b>  |
| <b>2. Where are the conditions defined under which compensation may be granted</b><br><i>If this regulation is different from the one mentioned under question 1, please indicate its title, date and date of entry into force</i>          | L <input type="checkbox"/> G <input type="checkbox"/> GNO <b>X</b> N<br><input type="checkbox"/> | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/> |
| <b>3. What does this compensation entail?</b> (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |  |   |
| a. Expense allowance<br>(please specify the type of expenses covered)   |  |   |
| b. Time off work<br>(please indicate duration)  |  |   |

|   |   |  |
|---|---|--|
| c. Compensation for discomfort endured (please specify)   |   |  |
| d. Refreshments (please specify)  |   |  |
| e. Others (please specify)  |   |  |
| f. If there are specific rules for certain types of tissues/cells, please specify   |   |  |
| <b>4. Are you aware of cases in your country where donors were given <u>remuneration</u> for the donation of tissues and cells?</b> | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/><br><br>If you answered yes, please specify: |  |

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>            | <b>Situation <u>after</u> the implementation of Directive 2004/23</b> |
|---|---|---|
| <b>1. Have measures been taken to <u>promote donation</u> of tissues and cells</b><br>(please tick the appropriate box)                 | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>               | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   |
| <b>2. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, donor days, ...) | European donor day<br>Information campaigns for haematopoietic stem cell donation | The same  |
| <b>3. Have measures been taken to <u>endeavour to ensure unpaid donation</u>?</b>   | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>               | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   |
| <b>4. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, ...)             | All information and awareness donor campaign emphasize the gratuity of donation.  |   |

#### IV. Promotion of the non-profit procurement of tissues and cells

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|  | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation <u>after</u> the implementation of Directive 2004/23</b> |
|--|---|---|
| <b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br>(please tick the appropriate box) | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   |
| <b>2. Please describe the type of measures taken and the parties involved in their implementation</b>  | The only procurement organizations and teams officially recognized are part of the National Health Service and as such both were on a non-profit basis. | It will not change.   |

#### V. Advertising

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>             | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>              |
|---|--|--|
| <b>Do you have regulation providing for 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?</b><br>(please tick the appropriate box) | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>                | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>                |
| <b>Type of regulation</b> (please tick the appropriate box)   | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> |
| <i>If this regulation is different from the one mentioned under question I, please indicate the title, date and date of entry into force of the regulation</i>  |  |  |
| <b>Describe the prohibitions</b>  |  |  |
| <b>Describe the restrictions</b>  |  |  |

## VI. Additional comments

If you have any additional comments or information please fill out the box below:

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|--|
|  |
|--|

# SWEDEN

## I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>                                 | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>  |
|--|---|---|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | <input checked="" type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N | <input type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N  |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  |   | Please see comments:<br>There has been no change. The Transplant act (1995:831) as well as the regulations and guidelines (SOSFS 1997) state the same thing voluntary and unpaid donation |
| <b>3. Date of the regulation</b><br>(dd/mm/yyyy)   |   |   |
| <b>4. Entry into force of the regulation</b><br>(dd/mm/yyyy)   | 01071996  | 01071996 for law and june 1997 for regulation   |

## II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|   | <b>Situation in the national regulation <u>before</u> the implementation of Directive 2004/23</b>                | <b>Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23</b>   |
|---|--|--|
| <b>1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?</b> | YES Yes<br>NO <input type="checkbox"/>   | YES <input type="checkbox"/><br>NO <input type="checkbox"/>  |
| <b>2. Where are the conditions defined under which compensation may be granted</b>                | L <input type="checkbox"/> G <input type="checkbox"/> GNO<br><input type="checkbox"/> N <input type="checkbox"/> | L <input type="checkbox"/> G <input type="checkbox"/> GNO<br><input type="checkbox"/> N <input type="checkbox"/><br>Actually it is not stated in the law or in the regulations that compensation is acceptable- No |

|   |                                      |   |
|---|--------------------------------------|---|
|   |                                      | change because of directive   |
| <i>If this regulation is different from the one mentioned under question 1, please indicate its title, date and date of entry into force</i>  |                                      |   |
| <b>3. What does this compensation entail?</b> (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |                                      |   |
| a. Expense allowance (please specify the type of expenses covered)  |                                      | Expenses for travel   |
| b. Time off work (please indicate duration)   |                                      | Yes   |
| c. Compensation for discomfort endured (please specify)   |                                      | No compensation for discomfort since this would come close to paying for organs and tissues |
| d. Refreshments (please specify)  |                                      | Possibly  |
| e. Others (please specify)  |                                      |   |
| f. If there are specific rules for certain types of tissues/cells, please specify   |                                      |   |
| <b>4. Are you aware of cases in your country where donors were given remuneration for the donation of tissues and cells?</b>  | YES <input type="checkbox"/>         | <b>NO</b> <input type="checkbox"/>  |
|   | If you answered yes, please specify: |   |

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>           |
|---|--|---|
| <b>1. Have measures been taken to <u>promote donation</u> of tissues and cells</b><br>(please tick the appropriate box)                 | YES <input type="checkbox"/> NO <input type="checkbox"/>               | YES <input type="checkbox"/> NO <input type="checkbox"/><br>Please see comments |
| <b>2. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, donor days, ...) |  | Please see comments   |
| <b>3. Have measures been taken to <u>endeavour to ensure unpaid donation</u>?</b>   | YES <input type="checkbox"/> NO <input type="checkbox"/>               | YES <input type="checkbox"/> NO <input type="checkbox"/><br>Please see comments |

|   |  |  |
|---|--|--|
| <b>4. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, ...) |  |  |
|---|--|--|

#### IV. Promotion of the non-profit procurement of tissues and cells

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|  | <b>Situation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>               |
|--|--|---|
| <b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br>(please tick the appropriate box) | YES <input type="checkbox"/> NO <input type="checkbox"/>               | YES <input type="checkbox"/> NO <input type="checkbox"/><br><br>Please see comments |
| <b>2. Please describe the type of measures taken and the parties involved in their implementation</b>  |  |   |

#### V. Advertising

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>                | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>                      |
|---|---|--|
| <b>Do you have regulation providing for 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?</b><br>(please tick the appropriate box) | YES <input type="checkbox"/><br><br><input type="checkbox"/>                          | YES <input type="checkbox"/><br><br>NO <input type="checkbox"/><br><br>Please see comments |
| <b>Type of regulation</b> (please tick the appropriate box)   | L <input type="checkbox"/> G <input type="checkbox"/><br>GNO <input type="checkbox"/> | L <input type="checkbox"/> G <input type="checkbox"/><br>GNO <input type="checkbox"/>      |
| <i>If this regulation is different from the one mentioned under question I, please indicate the title, date and date of entry into force of the regulation</i>  |   |  |
| <b>Describe the prohibitions</b>  |   |  |

|                                  |  |  |
|----------------------------------|--|--|
| <b>Describe the restrictions</b> |  |  |
|----------------------------------|--|--|

## VI. Additional comments

If you have any additional comments or information please fill out the box below:

### **Comments from Sweden**

There have been no changes so far in the legislation on donation and procurement of organs and tissues as a consequence of the Directive 2004/23/EC.

The same transplant act and the same National Board of Health and Welfare (1997: 4) regulations and guidelines are valid for organs as well as tissues.

The guiding principle is that donation of tissues and cells as well as of organs has to be voluntary and unpaid. Compensation for costs can be accepted but there is no remuneration and definitely no compensation for discomfort endured.

As far as reproductive cells are concerned the same principles apply according to the Laws on In vitro fertilization (1988:711) and Insemination (1984:1140) and in the Board of Health and Welfare regulations (binding) and guidelines (strong suggestions but not binding) SOSFS 2002:13

There is a suggestion from the Ministry of Health that there will be a new **Tissue act based on the Directive 2004/23/EC**.

It is expected that the new Tissue act will come into force during the second half of 2006.

It is quite clear that the Board of Health and Welfare will be called upon to issue regulations (binding) and guidelines (strong suggestions but not binding)

### **III**

#### **Promotion**

National promotion of the voluntary and unpaid donation of organs as well as tissues and cells is ongoing. There is now a National Council for Organ and Tissue Donation. One of the tasks of this council is to promote organ and tissue/cell donation. To be sure the focus of interest is on organ donation but tissues are always mentioned since the same laws and regulations apply.

### **IV**

#### **Promotion of the non-profit procurement of tissues and cells**

The procurement organizations and teams, all of them public and funded by society know that that procurement is a non profit activity

There are no laws prohibiting or restricting advertising the need for human tissues and cells. It simply is not done.

The professionals rely on the media to promote unpaid donation

**V** There is no **advertising** at the present time

*. "In the report from the Ministry of Health suggesting a Tissue act ( see above) it pointed out that advertising the need for tissues and cells *with a view to offering or seeking financial gain or comparable advantages* is illegal since it is in conflict with the Transplant act *and the law that regulates promotion*.*

# SLOVAKIA

## I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | Situation in the national regulation <u>before</u> the implementation of Directive 2004/23  | Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23                                 |
|--|---|---|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | <input checked="" type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N             | <input checked="" type="checkbox"/> L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N             |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  | Act No. 576/2004 Coll. of 22 September 2004 on healthcare, healthcare-related services and on the amendment and supplementing of certain laws | Act No. 576/2004 Coll. of 22 September 2004 on healthcare, healthcare-related services and on the amendment and supplementing of certain laws |
| <b>3. Date of the regulation</b><br>(dd/mm/yyyy)   | 21.10.2004  | 21.10.2004  |
| <b>4. Entry into force of the regulation</b><br>(dd/mm/yyyy)   | 01.01.2005  | 01.01.2005  |

## II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|   | Situation in the national regulation <u>before</u> the implementation of Directive 2004/23                                  | Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23               |
|---|---|---|
| <b>1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?</b>   | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>   | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>   |
| <b>2. Where are the conditions defined under which compensation may be granted</b>  | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/><br><input checked="" type="checkbox"/> N | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/><br><input checked="" type="checkbox"/> N |
| <i>If this regulation is different from the one mentioned under question 1, please indicate its title, date and date of entry into force</i>  |   |   |
| <b>3. What does this compensation entail?</b> (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |   |   |

|   |   |  |
|---|---|--|
| a. Expense allowance<br>(please specify the type of expenses covered)   |   |  |
| b. Time off work<br>(please indicate duration)  |   |  |
| c. Compensation for discomfort endured<br>(please specify)  |   |  |
| d. Refreshments<br>(please specify)   |   |  |
| e. Others (please specify)  |   |  |
| f. If there are specific rules for certain types of tissues/cells, please specify   |   |  |
| <b>4. Are you aware of cases in your country where donors were given <u>remuneration</u> for the donation of tissues and cells?</b> | YES <input type="checkbox"/> <input checked="" type="checkbox"/> NO<br><br>If you answered yes, please specify: |  |

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation <u>after</u> the implementation of Directive 2004/23</b> |
|---|--|---|
| <b>1. Have measures been taken to <u>promote donation</u> of tissues and cells</b><br>(please tick the appropriate box)                 | YES <input type="checkbox"/> <input checked="" type="checkbox"/> NO    | YES <input type="checkbox"/> <input checked="" type="checkbox"/> NO   |
| <b>2. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, donor days, ...) |  |   |
| <b>3. Have measures been taken to <u>endeavour to ensure unpaid donation</u>?</b>   | YES <input type="checkbox"/> <input checked="" type="checkbox"/> NO    | YES <input type="checkbox"/> <input checked="" type="checkbox"/> NO   |
| <b>4. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, ...)             |  |   |

#### IV. Promotion of the non-profit procurement of tissues and cells

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|  | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>   | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>  |
|--|--|--|
| <b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br>(please tick the appropriate box) | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO  | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO  |
| <b>2. Please describe the type of measures taken and the parties involved in their implementation</b>  | <b>§ 35 art. 8 Act No. 576/2004 Coll. of 22 September 2004 on healthcare, healthcare-related services and on the amendment and supplementing of certain laws</b> | <b>§ 35 art. 8 Act No. 576/2004 Coll. of 22 September 2004 on healthcare, healthcare-related services and on the amendment and supplementing of certain laws</b> |

#### V. Advertising

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>             | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>   |
|---|--|---|
| <b>Do you have regulation providing for 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?</b><br>(please tick the appropriate box) | YES <input type="checkbox"/> <input checked="" type="checkbox"/> NO                | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO<br>The update will be included in Act No. 576/2004 Coll. of 22 September 2004 on healthcare, healthcare-related services and on the amendment and supplementing of certain laws |
| <b>Type of regulation</b> (please tick the appropriate box)   | L <input type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> | L X G <input type="checkbox"/> GNO <input type="checkbox"/>   |
| <i>If this regulation is different from the one mentioned under question I, please indicate the title, date and date of entry into force of the regulation</i>  |  |   |
| <b>Describe the prohibitions</b>  |  |   |
| <b>Describe the restrictions</b>  |  |   |

## VI. Additional comments

If you have any additional comments or information please fill out the box below:

|  |
|--|
|  |
|--|

# SLOVENIA

## I. Regulation of the principle of voluntary and unpaid donation of tissues and cells

|  | Situation in the national regulation <u>before</u> the implementation of Directive 2004/23   | Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23 |
|--|--|---|
| <b>1. What is the type of regulation governing the principle of voluntary and unpaid donation of tissues and cells?</b><br>(please tick the appropriate box) | X L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N  | X L<br><input type="checkbox"/> G<br><input type="checkbox"/> GNO<br><input type="checkbox"/> N               |
| <b>2. Title of the regulation</b><br>(please add the full title and if possible an English translation)  | Zakon o odvzemu in presaditvi delov človeškega telesa zaradi zdravljenja (The removal and transplantation of human body parts for the purposes of the medical treatment act) | Law on transplant activities (draft)  |
| <b>3. Date of the regulation</b><br>(dd/mm/yyyy)   | 27/01/2000   | not yet adopted   |
| <b>4. Entry into force of the regulation</b><br>(dd/mm/yyyy)   | 10/03/2000   | not yet adopted   |

## II. Compensation for the donation of tissues or cells

Under the principle of voluntary and unpaid donation, **donors cannot be remunerated, but they may receive compensation** (making good the expenses and inconveniences related to the donation).

|   | Situation in the national regulation <u>before</u> the implementation of Directive 2004/23 | Situation in the national regulation as it is or will be <u>after</u> the implementation of Directive 2004/23 |
|---|--|---|
| <b>1. Are donors given any kind of <u>compensation</u> for the donation of tissues and cells?</b>   | YES X                      NO <input type="checkbox"/>                                     | YES X                      NO <input type="checkbox"/>  |
| <b>2. Where are the conditions defined under which compensation may be granted</b>  | L X   G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/>   | L X   G <input type="checkbox"/> GNO <input type="checkbox"/> N <input type="checkbox"/>                      |
| <i>If this regulation is different from the one mentioned under question 1, please indicate its title, date and date of entry into force</i>  | Zakon o zdravstvenem varstvu in zdravstvenem zavarovanju (12/08/2005; 01/09/2005)          | Zakon o zdravstvenem varstvu in zdravstvenem zavarovanju (12/08/2005; 01/09/2005)                             |
| <b>3. What does this compensation entail?</b> (the level and type of compensation may differ according to the type of tissues or cells concerned – if there are specific rules for certain types of tissues/cells, please specify under f.) |  |   |

|  |   |   |
|--|---|---|
| a. Expense allowance<br>(please specify the type of expenses covered)  | <i>travel expenses</i>  | <i>travel expenses</i>  |
| b. Time off work<br>(please indicate duration)   | <i>different from case to case<br/>(depends on medical opinion)</i>   | <i>different from case to case<br/>(depends on medical opinion)</i> |
| c. Compensation for discomfort endured<br>(please specify)   |   |   |
| d. Refreshments<br>(please specify)  |   |   |
| e. Others (please specify)   |   |   |
| f. If there are specific rules for certain types of tissues/cells, please specify  |   |   |
| <b>4. Are you aware of cases in your country where donors were given remuneration for the donation of tissues and cells?</b> | YES <input type="checkbox"/> NO <input checked="" type="checkbox"/><br><br>If you answered yes, please specify: |   |

### III. Promotion of the voluntary and unpaid donation of tissues and cells

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation <u>after</u> the implementation of Directive 2004/23</b> |
|---|---|---|
| <b>1. Have measures been taken to <u>promote donation</u> of tissues and cells</b><br>(please tick the appropriate box)                 | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   |
| <b>2. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising, donor days, ...) | information campaigns, donor days   | information campaigns   |
| <b>3. Have measures been taken to <u>endeavour to ensure unpaid donation</u>?</b>   | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   | YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>   |
| <b>4. Please describe the type of measures taken</b><br>(e.g. awareness raising or information campaigns, advertising,                  | information campaigns, donor days, education of lay and professional population, interviews of lay and professional population, | information campaigns   |

|      |   |  |
|------|---|--|
| ...) | professional and informative articles, www page, advertising with a purpose of education and correct information in different type of media |  |
|------|---|--|

#### IV. Promotion of the non-profit procurement of tissues and cells

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

|  | <b>Situation <u>before</u> the implementation of Directive 2004/23</b>  | <b>Situation <u>after</u> the implementation of Directive 2004/23</b>                                   |
|--|---|---|
| <b>1. Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?</b><br>(please tick the appropriate box) | YES X                      NO <input type="checkbox"/>  | YES X                      NO <input type="checkbox"/>  |
| <b>2. Please describe the type of measures taken and the parties involved in their implementation</b>  | information campaigns, education of lay population and professionals (Institute for Transplantation of Organs and Tissues of the Republic of Slovenia, Slovenian Transplant Society, Slovenian Medical Association), professional and informative articles, interviews of lay and professional population, www page, advertising with a purpose of education and correct information in different type of media | information campaigns (Institute for Transplantation of Organs and Tissues of the Republic of Slovenia) |

#### V. Advertising

|   | <b>Situation <u>before</u> the implementation of Directive 2004/23</b> | <b>Situation <u>after</u> the implementation of Directive 2004/23</b> |
|---|--|---|
| <b>Do you have regulation providing for 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</b> | YES X                      NO <input type="checkbox"/>                 | YES X                      NO <input type="checkbox"/>                |

|  |  |   |
|--|--|---|
| <b>comparable advantages?</b><br>(please tick the appropriate box)   |  |   |
| <b>Type of regulation</b> (please tick the appropriate box)  | L <input type="checkbox"/> G <input checked="" type="checkbox"/> GNO <input type="checkbox"/>                                    | L <input checked="" type="checkbox"/> G <input type="checkbox"/> GNO <input type="checkbox"/> |
| <i>If this regulation is different from the one mentioned under question I, please indicate the title, date and date of entry into force of the regulation</i> | The rule on procedures and activities on the field of procurement donors of the body parts for the purposes of medical treatment | The law on transplant activities (draft)  |
| <b>Describe the prohibitions</b>   | strictly forbidden   | not allowed   |
| <b>Describe the restrictions</b>   | restrictions according to the Penalty law  | not yet prescribed  |

#### VI. Additional comments

If you have any additional comments or information please fill out the box below:

# **THE UNITED KINGDOM**

## I. The principle of voluntary and unpaid donation of tissues and cells

### Question 1: What is the type of regulation governing the voluntary unpaid donation of tissues and cells

Situation in the national regulation before the implementation of Directive 2004/23  
(single choice question – compulsory)

G  
N

Situation in the national regulation as it is or will be after the implementation of Directive 2004/23

(single choice question – compulsory)

L

### Question 2: What is the name of the regulation(s) governing the voluntary unpaid donation of tissues and cells

Situation in the national regulation before the implementation of Directive 2004/23  
(open question – compulsory – please add the full title and if possible an English translation)

Direction issued 27 February 2001 accompanying A Code of Practice for Tissue Banking for Therapeutic Purposes

Situation in the national regulation as it is or will be after the implementation of Directive 2004/23

(open question – compulsory – please add the full title and if possible an English translation)

S32 of the Human Tissue Act 2004 prohibits commercial dealings in human material for transplantation.

In England, Wales and Northern Ireland, Section 32 of the 2004 Act (prohibition of commercial dealings in human material for transplantation) is already in force. It was commenced on 20 October 2005 by article 2(2) of the Human Tissue Act (Commencement No 3 and Transitional Provisions) Order 2005 S.I. 2005/2792 (appointed day). Until the equivalent provision in the Human Tissue Act 2006 in Scotland comes into effect on 1 September 2006, the Scottish Regulations implementing the Section will include a prohibition on commercial dealings.

### Question 3: What is the date of the regulation governing the voluntary unpaid donation of tissues and cells

Situation in the national regulation before the implementation of Directive 2004/23  
(open question – compulsory)

A Directive issued 27 February 2001 makes it clear that proper consent to donation must have been obtained and that commercial dealings in human organs and tissues are prohibited.

Situation in the national regulation as it is or will be after the implementation of Directive 2004/23

(open question – compulsory)

Human Tissue Act 2004 section 32 of the 2004 Act (prohibition of commercial dealings in human material for transplantation) is already in force. It was commenced on 20 October 2005 by article 2(2) of the Human Tissue Act (Commencement No 3 and Transitional Provisions) Order 2005 S.I. 2005/2792 (appointed day). The equivalent provision for Scotland is section 17 of the Human Tissue (Scotland) Act 2006 and the Regulations implementing the Directive..

**Question 4: What is the date of the entry into force of the regulation governing the voluntary unpaid donation of tissues and cells**

Situation in the national regulation before the implementation of Directive 2004/23

(open question – compulsory)

See above

Situation in the national regulation as it is or will be after the implementation of Directive 2004/23

(open question – optional)

See above

**II. Compensation for the donation of tissues or cells**

Under the principle of voluntary and unpaid donation, donors cannot be remunerated, but they may receive compensation (making good the expenses and inconveniences related to the donation).

**Question 5: Are donors given any kind of compensation for the donation of tissues and cells?**

Situation in the national regulation before the implementation of Directive 2004/23

(single choice question – compulsory)

YES in some limited live donor situations. For example the Anthony Nolan Trust will make all the arrangements for the donor of bone marrow and cover any financial loss incurred by their donors as a result of having donated blood stem cells (subject to prior agreement). A family member or friend is also able to accompany the donor. However, in most cases no compensation is made

Situation in the national regulation as it is or will be after the implementation of Directive 2004/23

(single choice question – compulsory)

- YES as above. In most situations no compensation will be made to the donor or to their family for the donation of tissue and cells

**Question 6: What does this compensation entail?**

You have the opportunity to specify your answers according to the type of tissues/cells concerned in question 7.

Situation in the national regulation before the implementation of Directive 2004/23

(multiple choice question – compulsory)

See above – this happens in a very limited number of situations

- Expense allowance
- Time off work
- Compensation for discomfort endured
- Refreshments
- X Others, please specify ...travel expenses for donor and one other person accompanying them., loss of earnings (where appropriate).....

Situation in the national regulation as it is or will be after the implementation of Directive 2004/23

(multiple choice question – compulsory)

As above

**Question 7: Specify the conditions for each type of compensation which may be granted.**

The level and type of compensation may differ according to the type of tissues or cells concerned. Therefore, you do not only have the possibility to inform us on the conditions for granting compensation in general, you can also specify the conditions per type of tissues/cells.

General overview of the conditions for each type of compensation

(open question – compulsory)

Expense allowance (specify conditions and type of expenses covered):

**See above – compensation is given in a very limited number of circumstances and depends on the individual circumstances of the donor**

Time off work (specify conditions and duration):

The donor could be compensated for loss of earnings

Compensation for discomfort endured (specify conditions):

No

Refreshments (specify conditions):

Tea and coffee only I suspect

Others (specify type of compensation and conditions):

Travel expenses to bone marrow transplant unit?

Do you want to provide information for a specific type of tissues/cells?

(single choice question – compulsory)

○ YES would really only be appropriate for the live donation of bone marrow in a limited number of circumstances

Overview of the conditions for each type of compensation for a specific type of tissues/cells

(open question – optional)

Specific type of tissues/cells concerned:  
See information given above

Expense allowance (specify conditions and type of expenses covered):

Time off work (specify conditions and duration):

Compensation for discomfort endured (specify conditions):

Refreshments (specify conditions):

Others (specify type of compensation and conditions):

Do you want to provide information on another type of tissues/cells?  
(single choice question – compulsory)

- YES
- NO

**Question 8: Where are the conditions defined under which compensation may be granted?**

Situation in the national regulation before the implementation of Directive 2004/23  
(single choice question – compulsory)

- N for tissues and cells (it is for organs)

*If this regulation is different from the one mentioned under question 2, please indicate the title, date and date of entry into force of the regulation*  
(open question – optional)

Title:  
Date of the regulation: dd/mm/yyyy  
Date of entry into force: dd/mm/yyyy

Situation in the national regulation as it is or will be after the implementation of Directive 2004/23

(single choice question – compulsory)

- L

*If this regulation is different from the one mentioned under question 2, please indicate the title, date and date of entry into force of the regulation*  
(open question – optional)

Title:  
Date of the regulation: dd/mm/yyyy or mm/yy  
Date of entry into force (optional): dd/mm/yyyy

### III. Promotion of the voluntary and unpaid donation of tissues and cells

#### Question 9: Have measures been taken to promote donation of tissues and cells

(single choice question – compulsory)

- YES

#### Question 10: Describe the type of measures taken to promote donation of tissues and cells (e.g. awareness raising or information campaigns, advertising, donor days, ...)

Situation before the implementation of Directive 2004/23

(open question – compulsory)

The promotion of donation generally is linked to campaigns to increase organ donation and include funded initiatives in hospitals, campaigns linked to GP registration, applications for driver licenses, Government funding of voluntary organisations, campaigns to raise awareness in ethnic populations, specific events (eg recent 10 year anniversary celebrations of our organ donor register) and many more initiative

Situation as it is or will be after the implementation of Directive 2004/23

(open question – compulsory)

These campaigns are ongoing and will continue after April 2006

#### Question 11: Have measures been taken to endeavour to ensure unpaid donation?

(single choice question – compulsory)

- YES – the general culture in the UK is that of altruistic and unconditional donation. Only in exceptional circumstances (such as outlined above) would donation be compensated

#### Question 12: Describe the type of measures taken (e.g. information campaigns, advertising, research on voluntary and unpaid donation...)

Situation before the implementation of Directive 2004/23

(open question – compulsory)

Guidance documents, letters to the service, web sites etc all promulgate the altruistic nature of donation

Situation as it is or will be after the implementation of Directive 2004/23

(open question – compulsory)

See above – this will continue after April 2006 with the added advantage of having legislation to make it perfectly clear that donation except in certain specified circumstances outlined in the Human Tissue Acts should be unpaid

#### IV. Promotion of the non-profit procurement of tissues and cells

This concerns measures taken in order to endeavour to ensure that procurement organisations and procurement teams work on a non-profit basis.

**Question 13: Have measures been taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis?**

(single choice question – compulsory)

- YES
- 

**Question 14: Describe the type of measures taken to endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis**

Situation before the implementation of Directive 2004/23

(open question – compulsory)

Guidance and Directions make it clear that there should not be commercial trafficking in tissues and cells (although the full costs of supplying the tissues may be recovered from the recipient organisations)

Situation as it is or will be after the implementation of Directive 2004/23

(open question – compulsory)

S32 of the The Human Tissues Act 2004 states:

**32 Prohibition of commercial dealings in human material for transplantation**

(1) A person commits an offence if he-

- (a) gives or receives a reward for the supply of, or for an offer to supply, any controlled material;
- (b) seeks to find a person willing to supply any controlled material for reward;
- (c) offers to supply any controlled material for reward;
- (d) initiates or negotiates any arrangement involving the giving of a reward for the supply of, or for an offer to supply, any controlled material;
- (e) takes part in the management or control of a body of persons corporate or unincorporate whose activities consist of or include the initiation or negotiation of such arrangements.

(2) Without prejudice to subsection (1)(b) and (c), a person commits an offence if he causes to be published or distributed, or knowingly publishes or distributes, an advertisement-

(a) inviting persons to supply, or offering to supply, any controlled material for reward, or

(b) indicating that the advertiser is willing to initiate or negotiate any such arrangement as is mentioned in subsection (1)(d).

(3) A person who engages in an activity to which subsection (1) or (2) applies does not commit an offence under that subsection if he is designated by the Authority as a person who may lawfully engage in the activity.

(4) A person guilty of an offence under subsection (1) shall be liable-

(a) on summary conviction-

(i) to imprisonment for a term not exceeding 12 months, or

(ii) to a fine not exceeding the statutory maximum, or

(iii) to both;

(b) on conviction on indictment-

(i) to imprisonment for a term not exceeding 3 years, or

(ii) to a fine, or

(iii) to both.

(5) A person guilty of an offence under subsection (2) shall be liable on summary conviction-

(a) to imprisonment for a term not exceeding 51 weeks, or

(b) to a fine not exceeding level 5 on the standard scale, or

(c) to both.

(6) For the purposes of subsections (1) and (2), payment in money or money's worth to the holder of a licence shall be treated as not being a reward where-

(a) it is in consideration for transporting, removing, preparing, preserving or storing controlled material, and

(b) its receipt by the holder of the licence is not expressly prohibited by the terms of the licence.

(7) References in subsections (1) and (2) to reward, in relation to the supply of any controlled material, do not include payment in money or money's worth for defraying or reimbursing-

(a) any expenses incurred in, or in connection with, transporting, removing, preparing, preserving or storing the material,

(b) any liability incurred in respect of-

(i) expenses incurred by a third party in, or in connection with,

any of the activities mentioned in paragraph (a), or

(ii) a payment in relation to which subsection (6) has effect, or

(c) any expenses or loss of earnings incurred by the person from whose body the material comes so far as reasonably and directly attributable to his supplying the material from his body.

(8) For the purposes of this section, controlled material is any material which-

(a) consists of or includes human cells,

(b) is, or is intended to be removed, from a human body,

(c) is intended to be used for the purpose of transplantation, and

(d) is not of a kind excepted under subsection (9).

(9) The following kinds of material are excepted-

(a) gametes,

(b) embryos, and

(c) material which is the subject of property because of an application of human skill.

(10) Where the body of a deceased person is intended to be used to provide material which-

(a) consists of or includes human cells, and

(b) is not of a kind excepted under subsection (9),

for use for the purpose of transplantation, the body shall be treated as controlled material for the purposes of this section.

(11) In this section-

"advertisement" includes any form of advertising whether to the public generally, to any section of the public or individually to selected persons;

"reward" means any description of financial or other material advantage.

Section 17 of the Human Tissue (Scotland) Regulations is in almost identical terms.

## V. Advertising

**Question 15: Do you have regulation providing for 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?**

Situation in the national regulation before the implementation of Directive 2004/23  
(single choice question – compulsory)

N

Situation in the national regulation as it is or will be after the implementation of Directive 2004/23  
(single choice question – compulsory)

L

**Question 16: What is the name of the regulation providing for 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?**

Situation in the national regulation before the implementation of Directive 2004/23  
(open question – compulsory – please add the full title and if possible an English translation)

Directions

*If this regulation is different from the one mentioned under question 2, please indicate the date and date of entry into force of the regulation*  
(open question – compulsory)

*Date of the regulation: dd/mm/yyyy*  
*Date of entry into force: dd/mm/yyyy*

Situation in the national regulation as it is or will be after the implementation of Directive 2004/23  
(open question – compulsory – please add the full title and if possible an English translation)

See s32 of the Human Tissue Act 2004 set out above, and section 17 of the Human Tissue (Scotland) Act 2006.

*If this regulation is different from the one mentioned under question 2, please indicate the date and date of entry into force of the regulation*  
(open question – compulsory)

*Date of the regulation: dd/mm/yyyy*  
*Date of entry into force: dd/mm/yyyy*

**Question 17: Describe the prohibitions**  
(open question compulsory)

See above

**Question 18: Describe the restrictions**  
(open question compulsory)

See above

## VI. Additional comments

If you have any additional comments or information please fill out the box below:

This form has been completed to cover the donation and procurement of conventional tissue and cells. It does not include reproductive cells – ie gametes and embryos