

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

### CHAPTER III

#### **DONOR SELECTION AND EVALUATION**

##### *Article 12*

#### **Principles governing tissue and cell donation**

1 Member States shall endeavour to ensure voluntary and unpaid donations of tissues and cells.

Donors may receive compensation, which is strictly limited to making good the expenses and inconveniences related to the donation. In that case, Member States define the conditions under which compensation may be granted.

Member States shall report to the Commission on these measures before 7 April 2006 and thereafter every three years. On the basis of these reports the Commission shall inform the European Parliament and the Council of any necessary further measures it intends to take at Community level.

2 Member States shall take all necessary measures to ensure that any promotion and publicity activities in support of the donation of human tissues and cells comply with guidelines or legislative provisions laid down by the Member States. Such guidelines or legislative provisions shall include appropriate restrictions or prohibitions on advertising the need for, or availability of, human tissues and cells with a view to offering or seeking financial gain or comparable advantage.

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

##### *Article 13*

#### **Consent**

1 The procurement of human tissues or cells shall be authorised only after all mandatory consent or authorisation requirements in force in the Member State concerned have been met.

2 Member States shall, in keeping with their national legislation, take all necessary measures to ensure that donors, their relatives or any persons granting authorisation on behalf of the donors are provided with all appropriate information as referred to in the Annex.

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*Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.*

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#### Article 14

##### **Data protection and confidentiality**

1 Member States shall take all necessary measures to ensure that all data, including genetic information, collated within the scope of this Directive and to which third parties have access, have been rendered anonymous so that neither donors nor recipients remain identifiable.

2 For that purpose, they shall ensure that:

- a data security measures are in place, as well as safeguards against any unauthorised data additions, deletions or modifications to donor files or deferral records, and transfer of information;
- b procedures are in place to resolve data discrepancies; and
- c no unauthorised disclosure of information occurs, whilst guaranteeing the traceability of donations.

3 Member States shall take all necessary measures to ensure that the identity of the recipient(s) is not disclosed to the donor or his family and vice versa, without prejudice to legislation in force in Member States on the conditions for disclosure, notably in the case of gametes donation.

#### Article 15

##### **Selection, evaluation and procurement**

1 The activities related to tissue procurement shall be carried out in such a way as to ensure that donor evaluation and selection is carried out in accordance with the requirements referred to in Article 28(d) and (e) and that the tissues and cells are procured, packaged and transported in accordance with the requirements referred to in Article 28(f).

2 In the case of an autologous donation, the suitability criteria shall be established in accordance with the requirements referred to in Article 28(d).

3 The results of the donor evaluation and testing procedures shall be documented and any major anomalies shall be reported in accordance with the requirements referred to in the Annex.

4 The competent authority or authorities shall ensure that all activities related to tissue procurement are carried out in accordance with the requirements referred to in Article 28(f).