

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

DIRECTIVE 2004/23/EC OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL

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on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(a) thereof,

Having regard to the proposal from the Commission⁽¹⁾,

Having regard to the opinion of the European Economic and Social Committee⁽²⁾,

Following consultation of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁽³⁾,

Whereas:

- (1) The transplantation of human tissues and cells is a strongly expanding field of medicine offering great opportunities for the treatment of as yet incurable diseases. The quality and safety of these substances should be ensured, particularly in order to prevent the transmission of diseases.
- (2) The availability of human tissues and cells used for therapeutic purposes is dependent on Community citizens who are prepared to donate them. In order to safeguard public health and to prevent the transmission of infectious diseases by these tissues and cells, all safety measures need to be taken during their donation, procurement, testing, processing, preservation, storage, distribution and use.
- (3) It is necessary to promote information and awareness campaigns at national and European level on the donation of tissues, cells and organs based on the theme 'we are all potential donors'. The aim of these campaigns should be to help European citizens decide to become donors during their lifetime and let their families or legal representatives know their wishes. As there is a need to ensure the availability of tissues and cells for medical treatments, Member States should promote the donation of tissues and cells, including haematopoietic progenitors, of high quality and safety, thereby also increasing self-sufficiency in the Community.
- (4) There is an urgent need for a unified framework in order to ensure high standards of quality and safety with respect to the procurement, testing, processing, storage and distribution of tissues and cells across the Community and to facilitate exchanges

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thereof for patients receiving this type of therapy each year. It is essential, therefore, that Community provisions ensure that human tissues and cells, whatever their intended use, are of comparable quality and safety. The establishment of such standards, therefore, will help to reassure the public that human tissues and cells that are procured in another Member State, nonetheless carry the same guarantees as those in their own country.

- (5) As tissue and cell therapy is a field in which an intensive worldwide exchange is taking place, it is desirable to have worldwide standards. The Community should therefore endeavour to promote the highest possible level of protection to safeguard public health regarding quality and safety of tissues and cells. The Commission should include in its report to the European Parliament and to the Council information on the progress made in this respect.
- (6) Tissues and cells intended to be used for industrially manufactured products, including medical devices, should be covered by this Directive only as far as donation, procurement and testing are concerned, where the processing, preservation, storage and distribution are regulated by other Community legislation. The further manufacturing steps are covered by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use⁽⁴⁾.
- (7) This Directive should apply to tissues and cells including haematopoietic peripheral blood, umbilical-cord (blood) and bone-marrow stem cells, reproductive cells (eggs, sperm), foetal tissues and cells and adult and embryonic stem cells.
- (8) This Directive excludes blood and blood products (other than haematopoietic progenitor cells) and human organs, as well as organs, tissues, or cells of animal origin. Blood and blood products are currently regulated by Directives 2001/83/EC and 2000/70/EC⁽⁵⁾, Recommendation 98/463/EC⁽⁶⁾ and Directive 2002/98/EC⁽⁷⁾. Tissues and cells used as an autologous graft (tissues removed and transplanted back to the same individual), within the same surgical procedure and without being subjected to any banking process, are also excluded from this Directive. The quality and safety considerations associated with this process are completely different.
- (9) The use of organs to some extent raises the same issues as the use of tissues and cells, though there are serious differences, and the two subjects should therefore not be covered by one directive.
- (10) This Directive covers tissues and cells intended for human applications, including human tissues and cells used for the preparation of cosmetic products. However, in view of the risk of transmission of communicable diseases, the use of human cells, tissues and products in cosmetic products is prohibited by Commission Directive 95/34/EC of 10 July 1995 adapting to technical progress Annexes II, III, VI and VII to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products⁽⁸⁾.
- (11) This Directive does not cover research using human tissues and cells, such as when used for purposes other than application to the human body, e.g. *in vitro* research or in animal

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models. Only those cells and tissues that in clinical trials are applied to the human body should comply with the quality and safety standards laid down in this Directive.

- (12) This Directive should not interfere with decisions made by Member States concerning the use or non-use of any specific type of human cells, including germ cells and embryonic stem cells. If, however, any particular use of such cells is authorised in a Member State, this Directive will require the application of all provisions necessary to protect public health, given the specific risks of these cells based on the scientific knowledge and their particular nature, and guarantee respect for fundamental rights. Moreover, this Directive should not interfere with provisions of Member States defining the legal term ‘person’ or ‘individual’.
- (13) The donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human applications should comply with high standards of quality and safety in order to ensure a high level of health protection in the Community. This Directive should establish standards for each one of the steps in the human tissues and cells application process.
- (14) The clinical use of tissues and cells of human origin for human application may be constrained by limited availability. Therefore it would be desirable that the criteria for access to such tissues and cells are defined in a transparent manner, on the basis of an objective evaluation of medical needs.
- (15) It is necessary to increase confidence among the Member States in the quality and safety of donated tissues and cells, in the health protection of living donors and respect for deceased donors and in the safety of the application process.
- (16) Tissues and cells used for allogeneic therapeutic purposes can be procured from both living and deceased donors. In order to ensure that the health status of a living donor is not affected by the donation, a prior medical examination should be required. The dignity of the deceased donor should be respected, notably through the reconstruction of the donor's body, so that it is as similar as possible to its original anatomical shape.
- (17) The use of tissues and cells for application in the human body can cause diseases and unwanted effects. Most of these can be prevented by careful donor evaluation and the testing of each donation in accordance with rules established and updated according to the best available scientific advice.
- (18) As a matter of principle, tissue and cell application programmes should be founded on the philosophy of voluntary and unpaid donation, anonymity of both donor and recipient, altruism of the donor and solidarity between donor and recipient. Member States are urged to take steps to encourage a strong public and non-profit sector involvement in the provision of tissue and cell application services and the related research and development.
- (19) Voluntary and unpaid tissue and cell donations are a factor which may contribute to high safety standards for tissues and cells and therefore to the protection of human health.
- (20) Any establishment may also be accredited as a tissue and cell establishment, provided it complies with the standards.

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- (21) With due regard to the principle of transparency, all tissue establishments accredited, designated, authorised or licensed under the provisions of this Directive, including those manufacturing products from human tissues and cells, whether subject or not to other Community legislation, should have access to relevant tissues and cells procured in accordance with the provisions of this Directive, without prejudice to the provisions in force in Member States on the use of tissues and cells.
- (22) This Directive respects the fundamental rights and observes the principles reflected in the Charter of Fundamental Rights of the European Union⁽⁹⁾ and takes into account as appropriate the Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on human rights and biomedicine. Neither the Charter nor the Convention makes express provision for harmonisation or prevents Member States from introducing more stringent requirements in their legislation.
- (23) All necessary measures need to be taken in order to provide prospective donors of tissues and cells with assurances regarding the confidentiality of any health-related information provided to the authorised personnel, the results of tests on their donations, as well as any future traceability of their donation.
- (24) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and the free movement of such data⁽¹⁰⁾ applies to personal data processed in application of this Directive. Article 8 of that directive prohibits in principle the processing of data concerning health. Limited exemptions to this prohibition principle are laid down. Directive 95/46/EC also provides for the controller to implement appropriate technical and organisational measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access and against all other unlawful forms of processing.
- (25) An accreditation system for tissue establishments and a system for notification of adverse events and reactions linked to the procurement, testing, processing, preservation, storage and distribution of human tissues and cells should be established in the Member States.
- (26) Member States should organise inspections and control measures, to be carried out by officials representing the competent authority, to ensure that tissue establishments comply with the provisions of this Directive. Member States should ensure that the officials involved in inspections and control measures are appropriately qualified and receive adequate training.
- (27) Personnel directly involved in the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells should be appropriately qualified and provided with timely and relevant training. The provisions laid down in this Directive as regards training should be applicable without prejudice to existing Community legislation on the recognition of professional qualifications.
- (28) An adequate system to ensure the traceability of human tissues and cells should be established. This would also make it possible to verify compliance with quality and

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safety standards. Traceability should be enforced through accurate substance, donor, recipient, tissue establishment and laboratory identification procedures as well as record maintenance and an appropriate labelling system.

- (29) As a general principle, the identity of the recipient(s) should not be disclosed to the donor or his/her family and vice versa, without prejudice to legislation in force in Member States on the conditions of disclosure, which could authorise in exceptional cases, notably in the case of gametes donation, the lifting of donor anonymity.
- (30) In order to increase the effective implementation of the provisions adopted in accordance with this Directive, it is appropriate to provide for penalties to be applied by Member States.
- (31) Since the objective of this Directive, namely to set high standards of quality and safety for human tissues and cells throughout the Community, cannot be sufficiently achieved by the Member States and can therefore, by reason of scale and effects, be better achieved at Community level, the Community may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.
- (32) It is necessary that the best possible scientific advice is available to the Community in relation to the safety of tissues and cells; in particular in order to assist the Commission in adapting the provisions of this Directive to scientific and technical progress in the light of the rapid advance in biotechnology knowledge and practice in the field of human tissues and cells.
- (33) The opinions of the Scientific Committee for Medicinal Products and Medical Devices and that of the European Group on Ethics in Science and New Technologies have been taken into account, as well as international experience in this field, and will be sought in the future whenever necessary.
- (34) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁽¹⁾,

HAVE ADOPTED THIS DIRECTIVE:

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- (1) [OJ C 227 E, 24.9.2002, p. 505.](#)
- (2) [OJ C 85, 8.4.2003, p. 44.](#)
- (3) Opinion of the European Parliament of 10 April 2003 (not yet published in the Official Journal), Council common position of 22 July 2003 ([OJ C 240 E, 7.10.2003, p. 3](#)), position of the European Parliament of 16 December 2003 (not yet published in the Official Journal) and decision of the Council of 2 March 2004.
- (4) [OJ L 311, 28.11.2001, p. 67.](#) Directive as last amended by Commission Directive 2003/63/EC ([OJ L 159, 27.6.2003, p. 46](#)).
- (5) Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivatives of human blood or human plasma ([OJ L 313, 13.12.2000, p. 22](#)).
- (6) Council Recommendation of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood in the European Community ([OJ L 203, 21.7.1998, p. 14](#)).
- (7) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components ([OJ L 33, 8.2.2003, p. 30](#)).
- (8) [OJ L 167, 18.7.1995, p. 19.](#)
- (9) [OJ C 364, 18.12.2000, p. 1.](#)
- (10) [OJ L 281, 23.11.1995, p. 31.](#) Directive as amended by Regulation (EC) No 1882/2003 ([OJ L 284, 31.10.2003, p. 1](#)).
- (11) [OJ L 184, 17.7.1999, p. 23.](#)