COMMITTEE OF MINISTERS
COMITÉ DES MINISTRES

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

MINISTERS' DEPUTIES Recommendations **CM/Rec(2020)5** 7 October 2020

Recommendation CM/Rec(2020)5[1] of the Committee of Ministers to member States on the quality and safety of tissues and cells for human application

(Adopted by the Committee of Ministers on 7 October 2020 at the 1385th meeting of the Ministers' Deputies)

The Committee of Ministers, under the terms of Article 15.b of the Statute of the Council of Europe,

Considering that the aim of the Council of Europe is to achieve greater unity between its member States and that this aim may be pursued, *inter alia*, by the adoption of common action in the health field;

Having regard to its Resolution Res(78)29 on harmonisation of legislations of member States relating to removal, grafting and transplantation of human substances and the final declaration of the 3rd Conference of European Health Ministers (Paris, 16-17 November 1987);

Having regard to Articles 3, 21 and 22 of the Convention on Human Rights and Biomedicine (ETS No. 164) and Articles 3 and 4 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning the Transplantation of Organs and Tissues of Human Origin (ETS No. 186);

Having regard to the Council of Europe Convention on Action against Trafficking in Human Beings (CETS No. 197) and the Council of Europe Convention against Trafficking in Human Organs (CETS No. 216);

Recalling its recommendations to member States Rec(94)1 on human tissue banks, Rec(98)2 on provision of haematopoietic progenitor cells and Rec(2004)8 on autologous cord blood banks (and its Explanatory Memorandum);

Having regard to 63rd World Health Assembly (WHA) Resolution WHA63.22 on human organ and tissue transplantation and the World Health Organisation (WHO) guiding principles on human cell, tissue and organ transplantation, as endorsed by 63rd WHA Resolution WHA63.22, May 2010;

Taking into account 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; Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells; Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells; Commission Directive (EU) 2015/565 of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells; Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells; and Commission Directive 2012/39/EU of 26 November 2012 amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells;

Taking into account the Barcelona Principles on the use of human donated tissue for ocular transplantation, research and future technologies;

[1] When adopting this recommendation, the Permanent Representative of Germany indicated that, in accordance with Article 10.2*c* of the Rules of Procedure for the meetings of the Ministers' Deputies, he reserved the right of his government to comply or not with the recommendation.

Considering that human tissues and cells can restore essential functions or, in some cases, save lives, but that the demand for some tissues and cells far outweighs the available supply;

Considering that human tissues and cells can be derived only from the body of a person – hence the ethical challenges associated with their use;

Considering that tissues from one deceased donor may be transplanted into as many as 100 patients and that some other tissues and cells can be provided only by living donors, as long as this procedure does not risk serious harm to the donor or endanger the donor's life;

Considering that, as with all material of human origin, human tissues and cells carry the risk of disease transmission that must be controlled by the application of scrupulous quality and safety requirements and by ensuring that comprehensive quality systems are in place;

Considering the importance of guidelines and standards to protect the health of living donors;

Considering the importance of registries to follow up recipients and donors;

Considering that haematopoietic progenitor cells need specific matching between a donor and recipient requiring international co-operation;

Considering the importance of training and education of health care professionals in the field of tissue and cell donation and transplantation to optimise care for donors and patients;

Considering that some tissues and cells are used practically unaltered from the condition in which they were removed from the donor but that others are processed into products that are almost unrecognisable as bodily material;

Taking into account that the rapid development of novel processing methods and clinical applications requires well-defined quality and safety criteria on which to base regulatory requirements;

Taking into account the need for harmonisation of principles and practices in member States;

Recognising, therefore, the need to provide health authorities, transplant organisations, tissue establishments, organisations responsible for human application of tissues and cells, including clinical users, with uniform standards for the quality and safety of tissues and cells for human application;

Recognising that the Guide to the quality and safety of tissues and cells for human application provides professionals with the most recent advances in the field, as well as technical guidance to ensure the quality, safety and efficacy of tissues and cells, ultimately improving the rate of successful and safe human application and ensuring the protection of living donors;

Aware that the Guide published by the Council of Europe has already become the generally accepted European standard and that it is therefore appropriate to give legal reference to this Guide;

Considering that this Guide is regularly updated by the Council of Europe European Committee on Organ Transplantation or, if necessary, a subordinate body;

Recommends that the governments of member States, having due regard to their national laws, rules and administrative provisions, take all necessary measures and steps to ensure that quality and safety standards for the donation, preparation and clinical application of tissues and cells are carried out in accordance with the guidelines set out in the appendix[2] to this recommendation.

Agrees that the Council of Europe European Committee on Organ Transplantation or, if necessary, a subordinate body, will regularly update this appendix.

[2] The appendix is available for free download at the EDQM website under the reference "Guide to the Quality and Safety of Tissues and Cells for Human Application". Any reference to this appendix should be read as referring to the most up-to-date version of this Guide.