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## **Recommendation CM/Rec(2020)4<sup>1</sup> of the Committee of Ministers to member States on the quality and safety of organs for transplantation**

*(Adopted by the Committee of Ministers on 7 October 2020  
at the 1385<sup>th</sup> meeting of the Ministers' Deputies)*

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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 3<sup>rd</sup> 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(2001)5 on the management of organ transplant waiting lists and waiting times, Rec(2003)12 on organ donor registers, Rec(2004)19 on criteria for the authorisation of organ transplantation facilities, Rec(2005)11 on the role and training of professionals responsible for organ donation (transplant “donor co-ordinators”), Rec(2006)15 on the background, functions and responsibilities of a National Transplant Organisation (NTO) and Rec(2006)16 on quality improvement programmes for organ donation;

Recalling its resolutions Res(78)29 on harmonisation of legislations of member States relating to removal, grafting and transplantation of human substances, CM/Res(2008)4 on adult-to-adult living donor liver transplantation, CM/Res(2013)55 on establishing procedures for the collection and dissemination of data on transplantation activities outside a domestic transplantation system, CM/Res(2013)56 on the development and optimisation of live kidney donation programmes, CM/Res(2015)10 on the role and training of critical care professionals in deceased donation, CM/Res(2015)11 on establishing harmonised national living donor registries with a view to facilitating international data sharing, CM/Res(2017)1 on principles for the selection, evaluation, donation and follow-up of the non-resident living organ donors and CM/Res(2017)2 on establishing procedures for the management of patients having received an organ transplant abroad upon return to their home country to receive follow-up care;

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

Taking into account Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation and Commission Implementing

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<sup>1</sup> When adopting this recommendation, the Permanent Representative of Germany indicated that, in accordance with Article 10.2c 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.

Directive 2012/25/EU of 9 October 2012 laying down information procedures for the exchange, between member States, of human organs intended for transplantation;

Considering the importance of life-saving organ transplantation and acknowledging that clinical requirement far outweighs availability of donated organs;

Considering that the misuse of organ transplantation may endanger human life, well-being and dignity and violate the principle of justice (including equity and fairness);

Considering that, as with all material of human origin, transplanted organs carry the risk of disease transmission that should be controlled by the application of scrupulous quality and safety requirements;

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 the importance of training and education of healthcare professionals in the field of organ donation and transplantation to optimise care for donors and patients;

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

Recognising, therefore, the need to provide health authorities, transplant organisations and clinical users with uniform standards for the quality and safety of organs for transplantation;

Recognising that the Guide to the quality and safety of organs for transplantation provides professionals with the most recent advances in the field, as well as technical guidance to ensure the quality and safety of human organs, ultimately improving the rate of successful and safe organ transplantation 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 a 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 organ donation and transplantation are set in place in accordance with the guidelines set out in the appendix<sup>2</sup> 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.

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<sup>2</sup> The appendix is available for free download at the EDQM website under the reference "Guide to the Quality and Safety of Organs for Transplantation". Any reference to this appendix should be read as referring to the most up-to-date version of this Guide.