Press release

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EDQM publishes 8th edition of the *Guide to the quality and safety of organs for transplantation*

The European Directorate for the Quality of Medicines & HealthCare (EDQM) has just published the 8th edition of the *Guide to the quality and safety of organs for transplantation*. The updated guide provides practical guidance to all professionals in the field, as well as technical guidance to ensure the safety and quality of human organs intended for transplantation. This extensively revised edition takes into account the latest developments and advances in the sector, with the objective of supporting professionals and improving the rate of successful and safe organ transplantation.

Petra Doerr, EDQM Director, stated on this occasion, "This important new edition includes a series of new features in what is already a fundamental reference in the transplantation field. In particular, a research agenda section has been included in most chapters, suggesting priority areas where evidence is insufficient. This is a crucial, forward-thinking step. It is essential that all professionals concerned have easy access to this information; this is why, as with previous editions, it can be downloaded for free on the EDQM website".

A dedicated working group with expertise in the field was convened for the elaboration of this guide, chaired by Beatriz Domínguez-Gil (Organización Nacional de Trasplantes, Spain) and Carl-Ludwig Fischer-Fröhlich (Deutsche Stiftung Organtransplantation, Germany). The group's exceptional contributions have ensured the preparation of this state-of-the-art technical guide, which is now made available and accessible to professionals and regulators by the EDQM.

New in the 8th edition

The revised guide contains instructions considered to be the "minimum standards" that align with the Council of Europe's fundamental principles and the relevant European Union (EU) directives in the field, in addition to advice based on best practices consistent with current scientific knowledge. It includes background information that should be considered in policy decisions, as well as in educational initiatives, by explaining the "why and how", and provides advance information and recommendations regarding emerging developments in the field.

The guide has been revised to present information ranging from the identification and referral of possible deceased organ donors to measuring outcomes in transplantation. It has dedicated chapters for each step of the donation and transplantation pathway, addressing both living and deceased donation, including the specificities of donation after the determination of death by neurologic criteria (DBD) or by circulatory criteria (DCD). It also contains a chapter on how to better address the communication of risk and crisis management.

Other revisions concern screening with regard to the possible transmission of disease (including COVID-19), psychosocial aspects of living donation, paediatric donation, guidance on severe adverse reactions and events, quality management and matters of consent, to name but a few.

Background

The work of the Council of Europe in the area of organ, tissue and cell transplantation started in 1987 and the secretariat of activities in this field is provided by the EDQM/Council of Europe.

The European Committee on Organ Transplantation (CD-P-TO), the steering committee responsible for transplantation activities at the EDQM, focuses on elaborating ethical, quality and safety standards in the field of transplantation, promoting the principle of non-commercialisation of organ, tissue and cell donation, and strengthening measures to avoid trafficking. It co-ordinates the activities of a number of ad hoc working groups, including those responsible for the elaboration of the *Guide to the quality and safety of organs for transplantation* and the *Guide to the quality and safety of tissues and cells for human application*.

Download and further information

For more information, visit the EDQM's dedicated web page and download the *Guide to the quality and safety of organs for transplantation*.

The *Guide to the quality and safety of tissues and cells for human application* (4th Edition, 2019), is also available.

For blood and blood products, please refer to the *Guide to the preparation, use and quality assurance of blood components* (20th Edition, 2020).

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Note for the Editor: Further information is available on the internet site **www.edqm.eu**.

The EDQM is a leading organisation that protects public health by enabling the development, supporting the implementation and monitoring the application of quality standards for safe medicines and their safe use. Its standards are recognised as a scientific benchmark worldwide. The European Pharmacopoeia is legally binding in member states.[1] The EDQM also develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

1. There are 40 members of the European Pharmacopoeia Commission: *Albania, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Türkiye, Ukraine, United Kingdom and the European Union.*

A political organisation set up in 1949, the Council of Europe works to promote democracy and human rights continent-wide. It also develops common responses to social, cultural and legal challenges in its 46 member states.