

Press release

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Guide to the quality and safety of organs for transplantation – EDQM releases 9th edition

The European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe is proud to announce the release of the 9th edition of the *Guide to the quality and safety of organs for transplantation* (Organ Guide). This comprehensive guide remains an essential resource for healthcare professionals and policy makers involved in organ donation and transplantation, providing updated safety and quality guidelines to support their activities.

Addressing critical needs in organ transplantation

Over the past few decades, transplantation therapies have seen great progress, significantly enhancing patient outcomes and quality of life. However, the persistent shortage of transplantable organs remains a major obstacle, preventing the full realisation of these advancements. In this context, comprehensive quality systems and appropriate donor screening and selection processes are essential to ensuring the safety and quality of organs for transplantation. The Organ Guide addresses these critical issues by offering detailed guidelines on setting up and enhancing procedures and processes at all stages of organ donation and transplantation, which is vital for both improving transplantation outcomes and reducing the risk of disease transmission or waste.

Petra Doerr, EDQM Director, stated on this occasion, "The 9th edition of the EDQM Organ Guide marks a major milestone in our ongoing efforts to address current and emerging public health challenges and priorities. The guide supports healthcare professionals and policy makers in designing and implementing the best possible donation and transplantation procedures, for the benefit of patients, donors and their families. This edition not only reflects the state of the art but also underscores our continued commitment to ethical practices and the non-remunerated donation of substances of human origin. We believe this guide will remain an invaluable resource for professionals dedicated to saving lives through organ transplantation."

Key features of the 9th edition

The 9th edition of the Organ Guide has been thoroughly revised to reflect the latest advancements in the field. All chapters have been updated to incorporate state-of-the-art practices and important new chapters have been added, covering topics such as principles and good practices in organ allocation, crisis management and contingency planning. Many chapters conclude with an updated research agenda, identifying priority areas where evidence is lacking, and "Take Note!" boxes have been added to highlight and summarise key extracts for quick reference.

Background

The Council of Europe has been setting standards in the area of organ, tissue and cell transplantation since 1987. The EDQM provides the secretariat for activities in this field. 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 for transplantation activities, promoting the principle of non-commercialisation of organ, tissue and cell donation, and strengthening measures to avoid trafficking. The CD-P-TO



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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

The 9th edition of the *Guide to the quality and safety of organs for transplantation* is currently available in English in both electronic and print formats, and the French version will also be available shortly. It can be downloaded from FreePub, the EDQM's free publications platform, and the print version is available for purchase from the EDQM WebStore. For more details, visit the EDQM website: https://go.edqm.eu/OTg.

EDQM technical guidance on SoHO

The EDQM provides in-depth technical guidance for all healthcare professionals working in the field of substances of human origin (SoHO). For more information, visit the EDQM's dedicated web pages.

The *Guide to the quality and safety of tissues and cells for human application* provides technical guidance to ensure the appropriate quality and safety of tissues and cells for human use.

The *Guide to the preparation, use and quality assurance of blood components* collates the most current scientific information available, offers guiding principles for donation and includes the Good Practice Guidelines (GPG) for blood establishments.

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

The European Directorate for the Quality of Medicines and HealthCare (EDQM) is a structural part of the Council of Europe. It traces its origins in the statute to the Convention on the Elaboration of a European Pharmacopoeia, opened for signature in 1964. Today, 39 member states of the Council of Europe have ratified the convention and more than 30 countries from all over the world participate in the EDQM activities as observers. The EDQM promotes and protects human and animal health by developing standards and supporting their implementation. It is active in four major policy areas: medicines, pharmaceutical care, substances of human origin and consumer health. EDQM staff represent almost 30 different nationalities and its work is supported by a network of nearly 2 000 experts from all over the world.

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