Press release

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EDQM releases new edition of the Tissue and Cells Guide, providing state-of-the-art guidance for healthcare professionals

The European Directorate for the Quality of Medicines & HealthCare (EDQM) has just published the 5th edition of the *Guide to the quality and safety of tissues and cells for human application*. The updated guide provides a comprehensive overview of the most recent advances in the field, as well as technical guidance on ensuring the quality and safety of human tissues and cells applied to patients. It is intended for healthcare professionals involved in all stages of the relevant activities, from identifying potential donors to the clinical application in patients and their follow-up.

Petra Doerr, EDQM Director, stated on this occasion, "This extensively revised edition takes into account the latest medical and scientific knowledge, data and techniques. It will further the objective of supporting professionals in improving the safety of tissues and cells and the efficiency of their clinical application. We thank the experts involved for their unfailing dedication and tireless work, all during the trying COVID-19 pandemic." She also highlighted the initiative of complementing the guide with an innovative online tool, the EDQM Microbiological Risk of Contamination Assessment tool (MiRCA). "This tool will help users – in particular tissue establishments, fertility clinics and health authorities – assess aseptic processes during the procurement and processing of tissues and cells, with significant benefits for public health in Europe and beyond."

New in the 5th edition

The 5th edition of the guide is divided into four parts and all chapters have been revised in detail.

- Part A covers general requirements applicable to all tissue establishments and organisations involved in the donation, procurement, testing, processing, preservation, storage and distribution of tissues and cells.
- Part B presents specific guidelines and requirements for the different substances of human origin.
- Part C contains good practice guidelines for tissue establishments.
- Part D contains tissue and cell monographs.

New content includes a section with guidance on assessing risks of deceased tissue donors with an antecedent or tumour diagnosis, new algorithms for the interpretation of infectious markers (HIV, HCV, HBV) and guidance on testing for bacterial endotoxins, bioburden testing and validating decontamination with antibiotics.

Other highlights of this edition include:

- the addition of a dedicated section on patient follow-up in all relevant chapters;
- updated guidance regarding medically assisted reproduction and fertility, including a special section on pre-implantation genetic testing;
- the new chapter "Tissues and cells as starting material", which provides guidance for authorised tissue establishments on quality and safety issues, mainly in donation, procurement, testing and distribution of the starting material for the production of novel therapies involving human tissues and cells.

Background

The work of the Council of Europe in the area of organ, tissue and cell transplantation started in 1987. The EDQM was entrusted with overseeing activities in this field in 2007. 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 tissues and cells for human application* and the *Guide to the quality and safety of organs for transplantation*.

Download and further information

For more information, visit the EDQM's dedicated web page and download the *Guide to the quality and safety of tissues and cells for human application*.

The *Guide to the quality and safety of organs for transplantation* (8th Edition, 2022), 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. The European Pharmacopoeia Commission comprises 40 members: 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.