Foreword and acknowledgments

Founded in 1949, the Council of Europe is the oldest and largest of all European institutions and now numbers 47 member states. One of its founding principles is that of increasing co-operation between member states to improve the quality of life for all Europeans.

Within this context of intergovernmental co-operation in the field of health, the Council of Europe has consistently selected ethical problems for study. One of the most important of these ethical issues relates to the non-commercialisation of human substances, i.e. blood, organs, tissues and cells.

In 2007, the Secretariat with responsibility for activities related to organ, tissue and cell transplantation was transferred to the European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe.

Transplant medicine and transplantation have progressed during recent decades in a way nobody would have imagined years before. The numbers of transplantations performed are only limited by organ availability. The availability of organs is very much dependent on how criteria for organ donation can be extended in relation to functional parameters and the risks of disease transmission.

Since 2002, the European Committee (Partial Agreement) on Organ Transplantation of the Council of Europe (CD-P-TO) has been publishing the Guide to the safety and quality assurance for the transplantation of organs, tissues and cells. This Guide dealt with different aspects of the transplantation process, from risk assessment to disease transmission. During the last revision process, it became evident that the fields of organ transplantation and tissue and cell transplantation have different safety and quality provisions and concerns, justifying
the existence of two different guides. Therefore, the CD-P-TO decided to separate the existing guidance into two new guides: one dealing with tissue and cell-specific requirements and the present guide dealing with organs. This 5th Edition of the *Guide to the quality and safety of organs for transplantation* collates updated information to provide transplant professionals with a useful overview of the most recent advancements in the field. To increase safety for patients on waiting lists and recipients of organs, it is essential that physicians in the process of detecting organ donors, transplant co-ordinators managing the donor process and the transplant physicians responsible for organ allocation have easy access to this information.

In this new edition, Chapter 1 (Introduction) has been updated to include important ethical principles that must always be respected in any donation and transplantation procedure. Chapter 2 (Assessment of donors) contains updated donor inclusion criteria. A new chapter, Chapter 3 (Management of the potential donor after brain death), has been added, summarising the most recent practices in Europe. Chapter 4 (Organ procurement and preservation) has been updated, particularly regarding new, emerging preservation techniques (e.g. machine perfusion). Chapter 5 (Risk of transmission of infectious diseases) has undergone major revisions to be completely up-to-date with recent developments in the field. In particular, the viral section has been extensively updated and a new section on multi-drug resistant bacteria has been included. Chapter 6 (Risk of transmission of neoplastic diseases) has been revised according to the most recent knowledge; in particular, new critical decision policies for primary cerebral malignancies have been introduced. Chapter 7 (Risk of transmission of other diseases) has been updated. An Index that will allow searches using keywords of interest has been created. Finally, this new edition has undergone for the first time a public consultation, which has allowed professionals and regulators from the different member states to review its entire content and to provide comments and suggest changes. When possible and relevant, their opinions have been taken into account and the text has been modified accordingly. Otherwise, when their comments involved extensive changes to the
text, they have been set aside and will be taken into account in the
next edition of the Guide.

For matters dealing with the use of tissues and cells, and blood and
blood products, please refer respectively to the Council of Europe
Guide to the quality and safety of tissues and cells for human applica-
tion and Guide to the preparation, use and quality assurance of blood
components.¹

This Guide has been the work of many people. The work has been
co-ordinated by the German Organ Transplantation Foundation
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¹ Council of Europe Organs, tissues and cells and Blood guides. More information
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All this has been a great combined effort, with extensive discussions dedicated towards the common goal of increasing safety, efficacy and quality in organ donation and transplantation. The final result is this Guide, which constitutes a common European standard, based on the long-standing expertise and knowledge of the EDQM.

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