

30 September 2015, Strasbourg, France NEW RESOLUTION CALLS FOR THE ESTABLISHMENT OF HARMONISED NATIONAL LIVING REGISTERIES TO FACILITATE INTERNATIONAL DATA SHARING

Transplant medicine has made such enormous progress during recent decades that the shortage of organs has now become the limiting factor in treating many patients with chronic organ failure. This large deficit in the supply of organs for transplantation seems set to continue into the future, even after deceased donation has been developed to its maximum therapeutic potential. Living organ donation, based on recognised ethical and professional standards, is therefore assuming increasing importance as a complementary means of meeting the shortfall, although there are big differences in the number of living donations performed among Council of Europe member States.

Ensuring the safety of the living donors is evidently a crucial consideration. However, it has become clear that the medical eligibility criteria, screening and after-care of the donors, including the follow-up and data registration protocols, vary enormously between the member States; some countries have a national living donor registry, while others do not.

In order to obtain sufficient information to define and secure proper follow-up of living donors, to document living donor prognoses and to investigate causal relationships between pre-donation risk factors, it is considered vital to compile harmonised data from the various countries with living donor programmes. This is the intention of a Resolution newly adopted by the Committee of Ministers of the Council of Europe on establishing harmonised national living donor registries with the view to facilitating international data sharing. The Resolution sets out the general guidelines for the construction of such national/international registries.

An additional <u>Explanatory Memorandum</u> accompanying this Resolution provides a detailed list of the parameters intended for inclusion in any national living donor registry, defining a mandatory data set and an expanded set of variables, as well as those to be included in a 'Registry of Registries' aimed at international data sharing.

The EDQM, Council of Europe, has been active in the field of transplantation since 1987. It actively promotes the non-commercialisation of organ donation, the fight against organ trafficking and the development of ethical, quality and safety standards in the field of organ, tissue and cell transplantation. It publishes a number of guides on the quality and safety of organs, tissue and cells for transplantation and an annual Newsletter Transplant, which collates international statistics on organ donation and transplantation throughout Europe and beyond.

All <u>Council of Europe Resolutions and Recommendations</u> are available to download on the EDQM website.

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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 development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark world-wide. The European Pharmacopeia is legally-binding in European Member States¹. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

¹There are thirty-eight members of the <u>European Pharmacopoeia</u> Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, the Former Yugoslav Republic of Macedonia, Turkey, Ukraine, United Kingdom and the European Union. There are twenty-eight observers: Albania, Algeria, Argentina, Armenia, Australia, Azerbaijan, Belarus, Brazil, Canada, China, Georgia, Guinea, Israel, Kazakhstan, Republic of Korea, Madagascar, Malaysia, Republic of Moldova, Morocco, Russian Federation, Senegal, Singapore, South Africa, Syria, Tunisia, United States of America, the Taiwan Food and Drug Administration (TFDA) and the World Health Organization (WHO).*

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 47 member states.