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Council of Europe reinforces transparency and safety of organ transplants carried out abroad

The Committee of Ministers of the Council of Europe has recently adopted *Resolution CM/Res(2017)2 on establishing procedures for the management of patients having received an organ transplant abroad upon return to their home country to receive follow-up*. This new resolution aims to protect all patients who have received an organ transplant, regardless of the circumstances in which it was obtained, and to safeguard public health by recommending that all patients undergoing organ transplantation are systematically registered in national transplant records.

While many countries are making notable efforts to develop and maximise their donation and transplantation programmes, there are exceptional circumstances in which some patients may be properly referred for transplantation abroad by their treating physicians. At the same time, organ shortages, or lack of access to a deceased-donor programme, have encouraged organ trafficking and human trafficking for the purpose of organ removal, often involving patients seeking to receive an organ transplant outside their home country. Patients who have received an organ transplant abroad, either upon referral of their treating physician or out of their own initiative, typically return to their country of origin shortly after the transplantation procedure to receive post-transplantation care. However, most countries do not systematically record in their national registries patients having received a transplant abroad, with their post-transplant care often limited to that provided by their physician upon returning home.

The new Resolution clearly establishes that the systematic and appropriate recording in national transplant registries of all patients who undergo organ transplantation ensures transparency, connection between traceability and bio-vigilance systems, and enables follow-up and evaluation of the long-term outcome of transplant patients. In the case of patients having received an organ transplant abroad, registration also allows provision of personalised care on the basis of latest epidemiological information from the country where the patient received the transplant. Finally, transplant registries also facilitate international exchange of information about patients receiving organ transplants abroad, allowing to better understand and analyse the phenomenon of travel for transplantation, identify hotspots for transplant tourism that may deserve investigation and combat illicit practices.

In summary, this welcome new Resolution will reinforce transparency of practices, facilitate traceability and contribute to the protection of public health by providing guidance on the appropriate management of patients having received an organ transplant abroad.

The full text of the *Resolution CM/Res(2017)2 on establishing procedures for the management of patients having received an organ transplant abroad upon return to their home country to receive follow-up can be found here:* <u>https://www.edqm.eu/sites/default/files/cmres_2017_2-on_establishing_procedures_for_patients_received_organ_tx_abroad.pdf</u>

Contact: Caroline Larsen Le Tarnec, Public Relations Division, EDQM, Council of Europe Tel.: +33 (0) 3 88 41 28 15 - E-mail: <u>caroline.letarnec@edqm.eu</u>



Note for the Editor: Further information is available on the internet site <u>www.edqm.eu</u> 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 Member States¹. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

¹There are thirty-nine 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, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, 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.

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.