

# STATEMENT ON A PROPOSED CONCEPT OF GLOBAL KIDNEY EXCHANGE

## European Union National Competent Authorities on Organ donation and transplantation

The European Union (EU) legislation requires that all transplant activities in the EU are carried out under the oversight of the National Competent Authorities (NCA).<sup>1</sup> This legislation requires that any exchange of organs with non-EU countries is authorised by the NCA of the EU Member State concerned.

The NCAs of the 28 EU Member States oversee safety and quality of more than 30,000 solid organ transplants performed annually under the EU transplant regulatory framework.<sup>2</sup> The NCAs also assess the appropriateness of any innovation related to organ donation and transplantation procedures.

In this context, the NCAs have discussed the Global Kidney Exchange (GKE) concept presented by Dr Rees of Toledo/US and Professor Roth of Stanford/US during a meeting of NCAs in Rome on 15 January 2018. The GKE concept is presented as a way to increase live kidney transplant opportunities at both High Income Countries (HIC) and Low and Middle Income Countries (LMIC)<sup>3</sup> and was further described in the American Journal of Transplantation<sup>4</sup>. In their review of the GKE concept, EU NCAs expressed concerns that the concept as currently presented may not be in line with the principles of organ donation and transplantation defined in EU legislation and practice. They consider that :

- GKE has the potential to infringe the fundamental principle of the non-payment for human organs, as it would provide funding for a kidney transplant procedure (surgery and related medical treatment) to a recipient from a LMIC in exchange for a donor who would facilitate a chain of transplants in a HIC;
- does not provide clear and adequate mechanisms to ensure the protection of the donor from the LMIC, neither during the selection process nor in the long-term, or the care of the recipient after the transplantation procedure has taken place and the recipient returns to their home LMIC;
- implies a risk of coercion of potential donors in LMIC, as they might be offered a direct or indirect financial gain in exchange for their kidney;

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<sup>1</sup> Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation. Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:207:0014:0029:EN:PDF>. Accessed: March 2018.

<sup>2</sup> Newsletter Transplant 2017. Available at: <https://register.edqm.eu/freepub>. Accessed: March 2018.

<sup>3</sup> Rees MA, Dunn TB, Kuhr CS, Marsh CL, Rogers J, Rees SE, et al. Kidney Exchange to Overcome Financial Barriers to Kidney Transplantation. Am J Transplant 2017; 17(3): 782-790.

<sup>4</sup> <https://www.ncbi.nlm.nih.gov/m/pubmed/27992110/?i=6&from=rees%20m%20financial>

- may have a negative impact on the development of local sustainable donation and transplantation programmes in LMIC as well as on initiatives to build ethically sound kidney exchange programmes with robust regulatory oversight.

**These concerns reflect concerns expressed by several other international bodies<sup>5,6,7</sup>**

**In the light of the concerns listed above, the NCAs consider it inappropriate for any transplant center in the EU to participate in the proposed GKE scheme as currently defined.**

**Nonetheless, the NCAs underline their full commitment to continue supporting the development of organ transplantation in LMIC and to share relevant EU expertise in the field. The NCAs are convinced that this must be achieved through support for local donation and transplantation programmes, organised by local professionals under the comprehensive oversight of local authorities.**

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5 Statement on the Global Kidney Exchange concept, as adopted at the 21st meeting of the Council of Europe European Committee on Organ Transplantation (CD-P-TO) on 10 April 2018, with the support of the Council of Europe Committee on Bioethics (DH-BIO). Available at: <https://www.edqm.eu/en/news/organ-transplantation-committee-warns-against-global-kidney-exchange-programme>

6 Statement Of The Declaration Of Istanbul Custodian Group concerning ethical objections to the proposed Global Kidney Exchange program. Available at: <http://declarationofistanbul.org/resources/policy-documents/795-statement-of-the-declaration-of-istanbul-custodian-group-concerning-ethical-objections-to-the-proposed-globalkidney-exchange-program>.

7 Posicionamiento de la Red Consejo Iberoamericano de Donación y Trasplante sobre el proyecto Global Kidney Exchange. Available at: <http://www.ont.es/publicaciones/Documents/NEWSLETTER%202014.pdf>. A