Standards of quality and safety of human organs intended for transplantation

2008/0238(COD) - 10/03/2015 - Follow-up document

The Commission presents a report on the exercise of the power to adopt delegated acts conferred to the Commission pursuant to Article 24 of Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation.

To recall, the Annex lays down the minimum data set which has to be collected for each donation as well the complementary data set data to be collected in addition, based on the decision of the medical team, taking into account the availability of such information and the particular circumstances of the case.

The Commission is empowered to adopt, delegated acts in order to supplement or amend both the minimum data set and the complementary data set. This power was conferred for a period of five years following 27 August 2010 and it requires the Commission to prepare a report in that respect not later than six months before the end of the five-year period.

The Commission has not yet used the delegated powers conferred by Article 24.

In 2011, the Commission, having consulted experts, concluded that the contents of the data set defined in the Annex to Directive 2010/53/EU were sufficiently detailed to ensure appropriate quality and safety standards, and were in line with current clinical practices in Member States. It considered that delegated powers should not be used at that stage, as there was no specific need for further details in the data set already defined.

The Commission is of the view that the delegated powers conferred by Article 24 of Directive 2010 /53/EU should remain in force. Transplantation medicine is evolving quickly. Therefore medical practices and scientific progress may require adaptation of the data set for organ and donor characterisation, for example with the inclusion of tests not previously available on a large enough scale to allow for their mandatory inclusion. Such a need may also arise in an emergency situation related to a new serious risk to human health, where the Commission may be required to adopt delegated acts through the urgency procedure, in accordance with Article 28 of the Directive.

In addition, the EU-funded project FOEDUS will come to an end in 2016 and will deliver guidelines and further consensus positions on organ and donor characterisation. This outcome will further support the Commission in assessing the need to amend the Annex to Directive 2010/53/EU.