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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the exercise of the power to adopt delegated acts conferred on the Commission pursuant to Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on the standards of quality and safety of human organs intended for transplantation

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1. Introduction

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[1] lays down rules to ensure standards of quality and safety for human organs (hereinafter 'organs') intended for transplantation into the human body, in order to ensure a high level of human health protection.

Article 7(1) of the Directive provides that organs and their donors must be characterised before transplantation through the collection of the information set out in the Annex to the Directive. Part A of the Annex lays down the minimum data set which has to be collected for each donation in accordance with Article 7. Part B of the Annex lays down 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.

2. Legal basis

Article 24 of the Directive empowers the Commission to adopt, in accordance with the specified conditions, delegated acts in order to:

a) supplement or amend the minimum data set specified in Part A of the Annex only in exceptional situations where it is justified by a serious risk to human health considered as such on the basis of the scientific progress;

b) supplement or amend the complementary data set specified in Part B of the Annex in order to adapt it to scientific progress and international work carried out in the field of quality and safety of organs intended for transplantation.

Article 25(1) confers to the Commission the delegated powers referred to in Article 24 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 delegated powers shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revoke them in accordance with Article 26. The

[1] OJ L 207, 6.8.2010, p. 14.

procedure to be followed in case of objections is set out in Article 27, while a possibility to adopt delegated acts under an urgency procedure is provided for in Article 28.

3. Exercise of the delegation

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

On 26 September 2011, the Commission convened a meeting of an expert group composed of Member States' experts in the field of organ donation and transplantation. Following discussions in this meeting and the consensus opinion of the group, the Commission 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. The experts also expressed their willingness to continue their work in relation to the content of the complementary data set through voluntary projects and guidelines, for example within scientific societies, European Organ Exchange Organisations and EU-funded projects.

As a result of this meeting, the Commission concluded 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 assessed that the first priority was the correct and timely transposition and implementation of all requirements laid down in Directive 2010/53/EU, including in its Annex. The Commission evaluated the content of the Annex as being sufficiently detailed and in line with medical practices and scientific state of the art in the transplantation field. In addition, the Commission, via EU-funding through the EU Health Programme, was and continues to be able to support Member States cooperation in the area of "organ and donor characterisation", in work packages of the EU-funded projects COORENOR (2010-2012) and FOEDUS (2013-2016).

4. Conclusion

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 (Article 24(a)) 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.