

*Exchange of views with the Commission on Human organs intended for transplantation*

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On April 24 2017, the European Parliament's Committee on Public Health held an exchange of views with the Commission on standards of quality and safety of human organs intended for transplantation, following the publication of first implementation report on this Directive. The representative of the Commission has marked this as a 'true EU success story', which the MEPs welcomed. However, the MEPs underlined some concerns on the differences between member states, organ trafficking and the issue of extensive waiting lists. Please find a summary of the debate below.

The Representative of the European Commission, first presented the implementation report on organs transplantation. He noted that this can be considered as a success story of the EU.

Moreover, he introduced some relevant figures. In 2015, more than 10,000 organ donations were carried out in the EU, resulting in more than 33,000 organ transplantations. This corresponds to a 29% increase since 2006, which is a result of major living donations and a significant increase from deceased donors. The increase is excellent news for EU patients, he said. Moreover, he explained that unfortunately still too many people die while on the waiting list. This needs to be constant reminder, he underlined.

He stressed that the increase can be seen in all member states, but there are also increasing differences between member states. For example, in Spain and recently also in Croatia, they had 40 donations per million inhabitants per year, which is among highest donation rates in the world. By contrast in other countries they have less donations.

He explained a similar picture for living donors, where the Netherlands and the UK are frontrunners. This figures clearly show that there is still enormous potential for better European cooperation. The member states should learn from each other how to do it better, he said, adding, like Croatia learned from Spain. This should be their focus.

Work of the Commission on organ donations and transplantations is based on two pillars. The Directive adopted in 2010 brings in minimum safety and quality standards for organ donations and transplantations and voluntary donations based on an Action Plan, which supports national authorities not only in areas covered by the legislation, namely, the efficiency of the organ transplant system and increased availability of organs. These requirements address the entire supply chain, from donation to transplantation, including the testing and transport.

In the first implementation exercise they focused on the question of whether the member states have introduced adequate oversight of the sector. They have found out that in line with the Directive, all member states have now established required competent authorities. However, the member states use different models to ensure the oversight (some have one authority and others have four). From their point of view this is completely acceptable as long as the rules are clear and adequate coordination takes place between all actors.

Another interesting aspect that they have observed during the implementation exercise is that member states allow procurement from medical teams from other member states. This makes a lot of sense, he underlined, as it is not useful that all member states would have transplant centres, which are very expensive. Like this

more organs are collected and used for the benefit of the patients. This is true European cooperation, he noted, based on solidarity and progress.

Then, he turned to the Action Plan, saying that the Commission funds projects, studies, etc. which allow national authorities to collaborate. Typical examples are twinning programmes, where experienced countries train less experienced countries, common training programmes for key actors (transplant coordinators), or most recent development of an IT platform, where member states can offer surplus organs. The latter was primarily used for organs donated by children. They have also created a working group with member states that developed a tool box for living donations. This tool box helps less experienced countries to develop such programmes. The Action Plan expired in 2015 and is currently under evaluation. The final report will be available before summer, he informed the MEPs.

In recent years, they have also received very significant funding from the European Parliament. Currently they run two major projects, one on chronic kidney diseases and one on raising social awareness. Lastly, he highlighted that organs do not only save lives, but they also save money. In this respect, he continued by explaining an example from the UK, whereby replacing dialysis treatment with kidney transplantation, the nation health system could save up to 80% or 5 million pounds every year. This comes together with improvement of the patients' quality of life and possibility to return to the labour market.

Gesine Meissner (ALDE, DE) said that she was disappointed on seeing that Germany is not a part of the cooperation. She was aware that Germany has some difficulties, therefore she asked how all this works (voluntary arrangement) in practice. She wondered if they have regular arrangements where all member states can come together or if it does depend on the separate arrangements between the member states. Moreover, she was interested in the cooperation between United Kingdom, Italy and Cyprus. In particular, she asked how this cooperation/partnership works and what brought them together and how it is with the transport, as they are geographically quite apart. Finally, she questioned if they have any specific numbers on the systems used in the EU.

Miriam Dalli (S&D, MT) welcomed the increase in total donations up to 29%. She said that there is still concern that the number of organs needed outstrips the supply. In this respect, she mentioned the problem of waiting lists and the number of patients on the lists. She said they should promote donations. She understood that the EU has limited competences to act as it concerns public health. Concerning the differences in the member states, she commented that some member states depend on bilateral agreements, meaning that this issue should be promoted at the European level and not just at the national level. Therefore, evolution of this matter is necessary. Finally, she asked the Commission about the cross-border exchange and what are representatives beliefs on the need for improvement. She asked what are the main steps and action that the EU as a whole could take to solve the issue of waiting lists and also to reduce the number of deaths of people while waiting for organs.

György Hölvényi (EPP, HU) noted the complexity of the issue and said that the Directive in place has resulted in an increase in cross-border cooperation. Moreover, he focused on illegal organ trafficking in the EU, which needs attention. Combating the trafficking of people for organ removal is an important issue and traceability remains a major concern. Finally, he underlined the importance of the training of health care people.

Mireille D'Ornano (ENF, FR) mentioned the issue of the number of transplantations made. Moreover, she focused on the problem of the consent arrangement. She wondered what the Commission's point of view is on the matter. She also asked the representative if the Commission will tackle the illegal trafficking issues in the future as well.

The Representative of the European Commission replied to MEPs as follows:

To Ms Meissner, he replied that all member states participate in the meetings of competent authorities and in many of working groups as well. He said that all member states de facto participate. For example, he said that Germany leads one of the projects that is funded by the European Parliament. On cooperation between United Kingdom, Cyprus and Italy, he said that they cooperate probably due to historic reasons, but there are also limitations within the cooperation, in particular when it comes to the transport (heart can travel 4-5 hours, kidney 24 hours). But if we look from another perspective – the distance from Cyprus to Italy, and between Italy and the United Kingdom, it is possible. Concerning the consent system, he stressed that ethical issues are national competence, therefore it all depends on the societal values. It is true that there are several different systems: opt-out system (17 countries using it), opt-in (7 countries, including Germany) and mixed system (4 countries). He wanted to underline that even if they have different systems the differences are not huge. In any case families are contacted to see what the donor's will is.

To Ms Dalli he agreed that there are still too many people on the waiting lists and many die waiting for organs. He believed that support of the Parliamentarians is important as they can bring the message to the national levels and also at the EU level. On cross-border exchange, he said that they have multi- and bi-lateral contracts. Multilateral ones are three systems at the moment: Euro-transplant (BENELUX, Germany, Austria, Hungary and Croatia), Scandia-transplant (Scandinavian countries) and Southern alliance (Italy, France and Spain). They have also introduced model contracts that have facilitate those exchanges between the countries.

On organ donation and trafficking, he noted that under EU law there is a prohibition on trafficking, but sometimes the reality is more complex, meaning that there are patients who go abroad in order to have a transplantation and the origin is not sometimes clear. Patients are also looking for organs online. Due to that he said that the good thing is that the competent authorities are looking into these issues very closely. In this issue they are not alone, he said, as the Council of Europe has adopted an agreement and the WHO will also adopt a declaration on this matter. Across the world they are trying to establish the principle that there should be no payment for organ donation/transplantation. He also agreed with Mr Hölvényi on the importance of training competent actors.

To Ms D'Ornano, he replied on the question of a consent system, saying that donation rates are not only dependent on consent but also on donations. He gave an example of Germany, where 80% of people involved, but nevertheless there have been some dramatic drops in donations due to recent scandals.