

THURSDAY 22 NOVEMBER 2007

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Present

Gale, B  
Howarth of Breckland, B (Chairman)  
Kirkwood of Kirkhope, L  
Lea of Crondall, L  
Neuberger, B  
Trefgarne, L  
Wade of Chorlton, L  
Young of Hornsey, B

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Witness: **Dr Eduardo Fernandez-Zincke**, Medical officer, European Commission, examined.

**Q1 Chairman:** Welcome. We are really grateful to you for taking the time to come and see us. This is an extraordinarily important inquiry that we have undertaken. We have had a lot of interest in the inquiry, from all sorts of groups, and we are hoping that the report that we make when we have heard the evidence will be of some value in the wider debate going on across the EU. Any help you can give us in starting us on this direction, as you are at the beginning of our inquiry, would be useful. Our specialist advisor, Professor Bobbie Farsides, is with us. She has been extremely helpful at the beginning in helping the Committee to understand what the issues are in relation to European donations. We have an hour for the session, which is open to the public. A transcript will be taken, a copy of which you will receive in a few days. Would you advise us, please, as quickly as you can, if there are any corrections to that transcript. Could you begin by stating for the record your name and your official title. You are then welcome to make a statement or to go straight into the questions. Perhaps you would tell us how you want to begin.

**Dr Fernandez-Zincke:** My name is Eduardo Fernandez-Zincke. I am a medical doctor. I work as a medical officer in the Directorate of Public Health and Risk Assessment, the

Directorate-General of Public Health and Consumer Protection of the European Commission. My Lord Chairman, I would like to thank this group and this Committee for giving the opportunity to the European Commission to be here, to explain to you the future proposals on the area of organ donation and transplantation that we are working on. I would prefer to go straight to questions, to try to make it as interactive as possible.

**Q2 Chairman:** Thank you very much indeed. You have had some advance notice of where we are, but could you begin by explaining the steps you propose to take in establishing a European Union level role in the field of organ donation and transplantation, including which future documents would be likely to be published and whether proposals for a new Directive or regulation are planned. Could you set out the likely timetable for this, so that, if you like, we have some legal and structural picture in order to begin inquiring.

**Dr Fernandez-Zincke:** Thank you, my Lord Chairman. I would like to start, if I may, with a short briefing of why the European Union is working in this area and what is the background of this communications that the Commission has adopted in May this year. I have to say that there are some milestones in the work of the policy on organ donation and transplantation of the European Union and I would like to go through these milestones as I think that could be useful to understand why we published this communication in May. The first milestone was the conference of Porto held in 2000 by the Portuguese Presidency which established the basis of the Community line, let us say, on organ donation and transplantation. At the very same, it was incorporated in the Treaty of the European Union, what is now known as Article 152, which gives competence to the Union on establishing the highest standards of quality and safety for human organs, blood and blood components, and substances of human origin. The second milestone, which was linked with the conclusions of the Porto conference, was a second conference organised by the Spanish Presidency in Malaga in 2001, which established the basis, the technical basis, for what is now known as the

Tissues and Cells Directive. One of the priorities that came out from the Porto conference was the need to work on quality and safety rules for tissues and cells. When the Commission was through the process of composition of the Tissues and Cells Directive, there was a lot of pressure already to introduce organs into the scope of the Tissues and Cells Directive and, at that time, the Commission took the approach that organs needed a completely different approach from the one having been taken for blood and for tissues and cells. There was a very helpful further milestone that I am going to mention, the conference in Venice, organised by the Italian Presidency, which established, with the conclusions, the main key elements in the area of organ donation and transplantation. With these conclusions, the Commission published a statement, together with the Tissues and Cells Directive, saying that organs are different from tissues and cells or blood, we have to consider that they are lifesaving treatments in most of the cases, we have to consider that there are enormous organ shortages in all European Member States and the quality and safety principles which are basic and which are important should always take into account this context in the area of organ transplantation. So that is why, in this statement, the Commission also committed to present an evaluation of the situation and a number of possible actions to carry out in the area of organ donation and transplantation, and the communication that we have adopted in May is the result of this evaluation that the Commission has carried out during these years and it is proposing a number of possible actions to be taken at Community level. I will now make a very brief statement of the content of the communication, in order that you have a complete context, and then I will go into the future steps, if that is correct for you. In the communication we identify three main challenges or three main areas where we have to work at Community level. The first one is what we call “transplant risks”. We know, and it is noted, that organ transplants pose a risk of transmission of disease from the donor to the recipient. This is not only a theoretical risk but we have had cases in the last years at the

European level where we have seen transmission of HIV, HTLV, malaria, rabies or malignant neoplasm from the donor to the recipient. And it is not only this, but many times an organ donor is also a tissues and cells donor, so there is a connection between the donation of organs and the risk and the donation of tissues and cells and the risks that that imposes. Also, in some cases, the transmission of diseases has affected more than one Member State. This is something that we could probably address later on in your following questions. The second challenge, which for the Commission is the main challenge that we have to address, is the organ shortage. We have more than 50,000 patients on the waiting list. There is a common problem that is facing all Member States and we think that this is the main problem that we will have to try to resolve. The third problem, which is probably a consequence of the second, is that of organ trafficking. There is the possibility that, given the situation of the scarcity of organs, there are some criminal organisations who are taking the possibility of exploiting vulnerable populations in order to take organs for patients in need. Taking these three challenges in mind, the communication is proposing three areas of action. The first one is to ensure quality and safety and responding to the core of the competence of the Treaty; the second is to increase organ availability or increase organ donation rates; and the third one is to make transplantation systems more efficient and more accessible. Because these are three different problems, the Commission thinks that all these problems cannot be solved with the same instrument, so we are proposing two different instruments. The first one is an action plan on the strength of cooperation between Member States. The second instrument, which complements this one, is the new legal framework that will establish the basic levels of quality and safety at Community level. After adopting the communication in May, the Commission have started working with national experts. Because we do want that this process should be as consultative and transparent as possible, we have already had three meetings with national experts, one in July, the second one in October and the third one last

week, on 20 November. The Commission is willing to introduce and has already introduced in the agenda of the legislative programme of the Commission of 2008 the possibility of presenting by then, 2008, a package of proposals on organ donation and transplantation which will be composed of the first instrument, an action plan on the strength of cooperation, where a Member State will have to identify which are the main priorities, and the second instrument, a new legal framework that should be flexible enough on one side to cover or to ensure the basic quality and safety rules and on the other side to respect and not to undermine donation rates in Europe.

**Chairman:** That is extremely helpful and clear, sorting out the issues and the timetable. Lady Neuberger, would you like to move on from that.

**Q3 Baroness Neuberger:** I think you have answered quite a lot of my second question in what you have already said. The bit of the question that, in a sense, you have not dealt with, is that there are members of the medical profession – and as a doctor yourself you will be only too well aware of this – who are worried that the EU package, when it emerges, may well over-bureaucratise what is already happening and not allow individual doctors or, indeed, transplantation programmes – to declare an interest, my brother-in-law is involved in one of those – to use their clinical expertise and judgment. You have said that you are bringing in the experts. To what extent can you give us reassurance that the experts feel thoroughly consulted and, indeed, are really contributing?

**Dr Fernandez-Zincke:** Thank you, Lady Neuberger. I think that is also our concern.

**Q4 Baroness Neuberger:** I should think so.

**Dr Fernandez-Zincke:** If you read the impact assessment which is attached to the communication, it is very clear that we are working in this line. In fact the approach that we are presenting to national experts differs from the blood and the tissue cell approach, in the

sense that what we want to construct is a system where you have to collect the needed information from the donor or from the organs and transmit this information to the transplant team, but we do not want to interfere in the clinical decision of the team. That is the main difference between the legal frameworks that we have in place and the future legal framework. I can say that we are trying to make an extraordinary effort to communicate this aim to the medical community. From the very beginning, they are invited in the discussion of the content, let us say, of the legal framework, and they are contributing – at least the national experts that are nominated by Member States. But we are not happy enough with this, so we are planning to create a group of medical professional, patients and other relevant stakeholders who will have the opportunity to comment on the content of both documents, the action plan and the legal framework. After all these consultations, we will anyway proceed in the normal way that the Commission does regarding these kind of documents, and an open consultation on our web page will be launched in order that everyone who wants to give their input into the content of the documents has the opportunity to do so.

**Q5 Lord Trefgarne:** I am very concerned to be assured, as I think Lady Neuberger is, that the Commission are not going to involve themselves in what are clinical matters. They are not going to be interfering in the clinical judgment of the consultant or for that matter in the various professional organisations within the Member States which, in many cases, are so distinguished. Can you give me that assurance?

**Dr Fernandez-Zincke:** I can give the assurance that that is the intention of the Commission. The intention of the Commission is not to interfere in the clinical decision. It is not to interfere in the healthcare system of Member States. That is why we are proposing a combination of two mechanisms. Even in the action plan there will be a number of measures intended to ensure quality and safety but we want to analyse which of the mechanisms of quality and safety should be in the legal mechanism and which should be in a national plan on

a more voluntary basis. We believe there are some initiatives that should remain in a legal mechanism, because they should be established in all transplant systems, because no transplant system could work without these guarantees, but also we think that some measures intending to improve the quality of transplant should go into the other mechanism, which should be created on a more voluntary basis and taking into account the participation of the professionals.

**Q6 Lord Trefgarne:** There is likely to be a Directive resulting from all of this.

*Dr Fernandez-Zincke:* I think that the intention of the Commission is to have a Directive for one side plus an action plan on the other side. But of course you have to establish an impact assessment and try to analyse the different impacts.

**Q7 Lord Trefgarne:** Which article of the Treaty will that Directive come under?

*Dr Fernandez-Zincke:* 152.

**Chairman:** This leads in very well to Lord Wade's questions, I think.

**Q8 Lord Wade of Chorlton:** Thank you. I have a couple of questions that cover the current position and then some on what the longer-term objectives are. How would you characterise the present quantity and quality of organ donation and transplantation services across the EU? What do you see are the realistic aims for the short- and longer-term future in improving the quantity and quality of organ donation and transplantation services across the EU? In other words, how do you see they are now and how do you think they will improve as a result of these Directives?

*Dr Fernandez-Zincke:* I will start probably with the quantity and then we can go to the quality. I have to say that we have in mind two mechanisms, not only a Directive but also an action plan in order to strengthen cooperation between Member States. I have to say that, in

general, organ shortage is a problem that is facing all Member States, so it is a common problem in Europe and in the world. The average donation rate of the European Union is 18.8 per million of population. If you compare this average with, for example, the average of the US, the US have achieved an average donation rate of 25.5 per million of population, so we are below. But what is more important, I think, is that the situation at the European level is not homogeneous. There is a wide variability of organ donation rates between Member States, which runs from 35.1 per million of population in some Member States to less than one per million of population in other Member States.

**Q9 Lord Kirkwood of Kirkhope:** To less than one?

*Dr Fernandez-Zincke:* Yes, it is 0.8 in some Member States, so practically non-existent. That is also transferred to a wide variability on transplantation activities. It is not only the donation part but also the transplantation activities, which rise from 1.6 to 57.6 per million population, depending on the Member State, in the case of kidney transplantation, or from 0.8 to 24 per million population in the case of liver transplantation. So, again, there is a wide variability between Member States. In Europe there were approximately 58,000 persons on the waiting list in 2006. I have mentioned some figures now regarding deceased donations and transplantation from deceased donors, but, if we look to living donations, the activity of living donations also varies completely in different Member States. In some Member States, 100 per cent of the activity of kidney transplantations is coming from living donors; in other Member States, no living donation programmes are open. So, again, there are different experiences and different situations that vary widely. This situation of not being homogeneous also applies if you see the situation of waiting lists: how waiting lists are managed in different Member States; the sizes of waiting lists in different Member States; the conditions to include patients in the waiting lists in different Member States. That is also interesting: if you look to public awareness and if you look to the willingness to donate in the

different Member States, that also varies widely from one to the other, and if you look to some indications like family refusals, the refusal of a family at the moment of the donation, that varies from 15/20 per cent in some Member States to more than 40 per cent in some Member States. If you combine these two indicators and you analyse for one side the willingness to donate of the population and the actual donation rates, you can see that these two figures are not always correlated. That means that in some Member States they have not enough success in transferring the willingness to donate into actual donation rates or, saying this in another way, some Member States have more success than others in doing so.

**Q10 Chairman:** We are almost halfway through our time and we have a long way to go. Your answers are superb and we are certainly going to want to have everything you have to give us, but I want to give some other members of the Committee the opportunity.

**Dr Fernandez-Zincke:** Thank you, my Lord Chairman. May I just mention one feature on quality and safety because there was a second part to your question. I think we have made a survey in 2003 on the situation of quality and safety systems in Europe and I also want to add that, again, there is a wide variability. There are some Member States who have all the systems in place and there are some Member States who do not have.

**Q11 Lord Wade of Chorlton:** To sum that up, you are saying that one of the objectives and one of the things we ought to see happen is much more equalisation of these services throughout Europe. The main method has to be in the areas that are weak rather than the areas that are strong.

**Dr Fernandez-Zincke:** I think that you have expressed it very well. I think we have to use the best practice and the experience of some Member States in trying to help other national systems in increasing their level of performance.

**Q12 Lord Wade of Chorlton:** The other question is what views do you have on the need for the EU to coordinate the policies relating to organ donation and transplantation with the health policies designed to reduce the prevalence of lifestyle-related diseases?

*Dr Fernandez-Zincke:* Absolutely, I think, this is a key question. Health prevention and health promotion policies have always been in the core, let us say, of the objectives of the European Union and, also, in the core of the public health problem of the European Commission. I think the Commission has adopted recently what is called the Health Strategy, a strategy that tries to be a comprehensive framework that brings together many new policies to work towards health goals, and I think that both the prevention and the promotion policies and the transplantation policies are included in the Health Strategy. I do not think we have to see this as a kind of competition between them but as a kind of complementary approach to a number of diseases.

**Lord Wade of Chorlton:** Thank you very much.

**Chairman:** Can we move on to Lady Young.

**Q13 Baroness Young of Hornsey:** My question concerns ways for improving the supply of organs for transplantation. Particularly with regard to the much higher organ donation rate in Spain, than is in the UK, what do you think is the relative importance for improving the supply of organs for transplantation, between, let us say, improving organ donation and transplantation services and, on the other hand, switching possibly from a system of opting in, which is what we do here to identify potential donors, to a system of opting out or this idea of presumed consent?

*Dr Fernandez-Zincke:* Thank you, Lady Young for your question. I can try to answer from my personal experience and my opinion. I think the key elements of the success of Spain in having the highest donation rate in the world is mainly because of the organisational system and the model of organisation that they do have. I think the Spanish model could be

summarised in six elements: (i) a transplant coordinating network with a key person in all the hospitals who is in charge of the donation in that hospital and who belongs to the staff of this hospital; (ii) quality programmes which are evaluating continuously the performance of donations in the different hospitals; (iii) a competent authority of central office which is supporting all the system; (iv) a great effort in training professionals how to detect a donor, how to talk with the family, how to maintain the donor and how to follow up all those procedures; (v) hospital reimbursement. It is very important for the Spanish model to incentivise the hospital of donation: if a hospital sees that donation is a burden more than an incentive, then the donation rates will probably vary a lot. I think we have to incentivise hospitals to, let us say, promote organ donation; and (vi) a close attention to the media. I think that during these two decades the system in Spain has constructed a very important trust in the population. It has been built by establishing permanent contact with the media and by improving the media skills of professionals, mainly health professionals, who are part of the system. There is an important debate – and it is not only in the UK – about presumed consent and informed consent. I have to say, after reading a number of papers, that there is not a conclusive result of this, mainly because many of the presumed consent systems, like the Spanish system, do not apply the presumed consent law in a very restrictive way. In Spain, all families are asked before performing the donation. It is a presumed consent law which is applied in practice giving a lot of importance to the opinion of the next of kin.

**Q14 Baroness Young of Hornsey:** Are you saying that, because of the systems you have evolved in Spain, there is much more confidence in the system and that is the important factor rather than this strict adherence to a notion of presumed consent?

**Dr Fernandez-Zincke:** I think that the presumed content law in Spain gives, in a way, a guarantee to the professionals, but I think that the main element of the success of Spain is the organisational model.

**Q15 Chairman:** It is more structural than cultural, if you like.

*Dr Fernandez-Zincke:* Yes. Absolutely.

**Chairman:** That is an interesting point.

**Q16 Lord Trefgarne:** Are you Spanish?

*Dr Fernandez-Zincke:* Yes, I have to say that I am Spanish.

**Chairman:** This structural/cultural issue will come into Lord Kirkwood's point too, which is about cross-border donations.

**Q17 Lord Kirkwood of Kirkhope:** Thank you. Good morning. I have a very simple and apparently naïve question to ask: what would be the principal two or three benefits to widening the number of nations that are involved in a scheme within Europe? At the moment there are six or seven, they are functioning well, and you have given us some interesting statistics, but what would be the two or three key things that would be different if we made this Europe-wide?

*Dr Fernandez-Zincke:* Thank you for your question, Lord Kirkwood. I think you are mentioning the example of Eurotransplant as a kind of regional structure of cooperation. I think the example of Eurotransplant shows that, once a common organisation and common rules are in place, the number of organs has since increased and contributes to maximise the opportunity for patients to obtain the best possible organs.

**Q18 Lord Kirkwood of Kirkhope:** Have you done any risk analysis of that. You are asserting that, and I guess it is true, it would seem to be logical, but have you done any modelling, any analysis or assessment?

*Dr Fernandez-Zincke:* I have to say that I personally have not done any risk analysis on this and it probably should be done. I think the Eurotransplant area has some studies on showing these results.

**Q19 Lord Kirkwood of Kirkhope:** If they exist, could we have access to them?

*Dr Fernandez-Zincke:* I will try my best.

**Q20 Lord Kirkwood of Kirkhope:** That is very kind. Thank you.

*Dr Fernandez-Zincke:* What I wanted to say is that regional cooperations have importance in a number of issues; for example, if you are in a very small Member State, with a very small donor pool, and you have a potential donor but you do not have a recipient on the waiting list, this donor will never be used. The second thing is that if you have an urgent patient – in many cases you have a hepatitis fulminating that requires a liver in three days – obtaining this organ on time could happen in Spain, it could happen in France, it could happen in Eurotransplant but it will be very difficult in Malta or in Cyprus or the other smaller Member States. For those cases it would be advantageous to organise a more extensive donor pool. Other examples could be, for example, a paediatric patient who requires a specific type of organs or those patients who are known as hypersensitised patients, patients who need organs that really match completely, again, extending the donor pool in this situation could help, let us say, the performance of the system. It does not mean that it has to be a European system. That is not the intention of the Commission. The idea is that probably regional cooperations will be really a very good idea in order to increase the performance of the transplantation system and efficiency.

**Lord Kirkwood of Kirkhope:** So it is a bigger pool. Thank you very much.

**Q21 Chairman:** You have said quite a lot on quality and safety already. Is there anything else you would like to add that has not been already said on quality and safety? Because you said a lot in your introduction. It is clearly a key area, is it not?

**Dr Fernandez-Zincke:** I think it is a key area. I think that probably you could find in the communication the key principles that we would like to introduce and include into the legal framework. I probably can underline again that there are elements of quality and safety that probably will go into the action plan but not into the legal framework. That is the idea behind the Commission, after consulting some experts. For example, one element that we are not considering to introduce into the legal framework but on which we are trying to build a consensus between Member States, is the evaluation of post-transplant results, that is a measure of the quality of the transplantation. That never will or should go, in our opinion, into a legal, binding requirement but will be a collaborative action between Member States.

**Chairman:** That is clearly an area we need to look at. Could we move on to Lady Gale, who is going to deal with another area.

**Q22 Baroness Gale:** My question is on organ trafficking. Do you perceive there is a problem of organ trafficking across the EU? To what extent do you think there is a potential for this to become an even greater problem in the future? What role could there be at an EU level to monitor and combat any growth in the problem of organ trafficking?

**Dr Fernandez-Zincke:** Thank you, Lady Gale, for your question. I think the problem of organ trafficking in the European Union is not a major problem. I think it is very scarce, the cases that have been denounced of organ trafficking happening in the European Union Member States. The first role of the Commission probably in this area is always to have investigated and contacted with competent authorities in the Member States, in case of any suspicion of possible organ trafficking in the EU. Also, we have extended the mandate of Europol in order to be combating the existence of these kinds of cases, but, as I said, I do not

think this is a major problem in the European Union. I think the type of organ trafficking that is a problem and which is happening – we have data – is when citizens, also European citizens, are going abroad to third countries to have an organ from the local populations in these countries. The Commission is working together with the World Health Organisation and with the Council of Europe in order to monitor also this situation in third countries. As far as our competence makes us competent to do something, we will try to avoid the situation, as has been mentioned also in the communication, but I think that, in this case, mainly it remains the competence of Member States. Probably where we can play a role is to try to agree with Member States common national positions regarding this problem.

**Q23 Lord Lea of Crondall:** Could I ask where organ trafficking becomes legal trafficking? I am very sorry, I have come in halfway through the discussion but presumably there is some subconscious worry that my organ might go somewhere I did not want it to go. Have you come across such a concept? Do you think people perhaps do not realise that they can get a better match if they do go to a wider area? Presumably people do pay money, do they, in the official arena?

**Dr Fernandez-Zincke:** Thank you for your question. There is not any Member State in the European Union which allows the paying for human organs. This is obviously a debate that is probably happening in other parts of the world, mainly, probably, in the US, but even in the US this is not allowed. I think that basic ethical principles which are enforced in all Member States prohibits the payment for human organs for transplantation.

**Chairman:** Thank you very much indeed. That is extremely helpful. It would be helpful for the Committee if we could move on, out of order, to Lord Trefgarne, who is going to ask about the ethical issues, because he has to leave very promptly. With the Committee's indulgence perhaps it would be possible for us to move on to the ethical issues next.

**Q24 Lord Trefgarne:** Thank you very much, my Lord Chairman. What have your investigations revealed as to the ethical concerns which presumably arise between different Member States in relation to this matter? How do you think these issues can be handled most sensitively to ensure that they do not interrupt the orderly flow of donation services while at the same time having regard to the sensitivities? The related issue is whether you are going to have to define more carefully the so-called point after death at which organs may be taken from donors. Is this when breathing ceases or when the heartbeat ceases or when brain-stem death is assumed to have occurred?

*Dr Fernandez-Zincke:* Thank you for your question. I would like to start stating that it is not the intention of the European Commission to harmonise ethical issues. I think we have a wide variability of social talk around religious values in Europe which does not make it possible, and it is not within our competence, to harmonise, let us say, the ethical issues. Saying that, I think I have elaborated a list of the main ethical issues linked with organ transplantation because this is a field which has a number of elements which are very important on ethical grounds. The first one is the need for consent. This is something that has to be very clearly stated in all Member States. It is not the intention of the Commission to say how consent should be organised the different Member States but, as we have done with the Tissue and Cells Directive, it is important to stress the need of consent, however the Member States organise this consent.

**Q25 Lord Trefgarne:** It is not going to be assumed consent.

*Dr Fernandez-Zincke:* No.

**Q26 Lord Trefgarne:** It will be positive consent.

*Dr Fernandez-Zincke:* It will be a need for consent and then I think Member States should choose the preferable options that they consider are more appropriate for their own societies,

let us say. It is not something that will be coming from the European Union. The second element is the question of commercialisation of human organs. It is the question of ensuring voluntary and unpaid donations for organs, which I think is kept in the chapter from the fundamental rights of the European Union which says that there should not be financial gain from the parts of the human body, as such. I think that is, again, something that is already endorsed or promoted in the Blood Directive and in the Tissue and Cells Directive and I think it is something that is a basic principle where we are working on it. The third element is probably data protection and confidentiality of the organ donors. I think that is a principle that has been already announced before in the previous pieces of work. The other aspect that is important in the organ field is of course the allocation criteria of organs.

**Q27 Lord Trefgarne:** Before you move away from the area, have you take into account the various religious concerns? We have been seeking guidance from various people and we have not had very much. Have you had any representations of that kind? Have you taken them into account?

**Dr Fernandez-Zincke:** I think that taking into account the religious groups is very important in trying to make a policy on organ transplantation. In fact, last week, I was in a meeting at the Vatican and we had a discussion on organ donation and transplantation. We have asked, also Member States' national experts what are their experiences regarding different ethnic and religious groups for organ donation and transplantation. But, again these are questions that – and I want to insist on this – are the subject of subsidiarity. It is something on which we could cooperate and put on the table.

**Q28 Lord Trefgarne:** What did they tell you in the Vatican?

**Dr Fernandez-Zincke:** I think the Catholic Church is one of the churches which is more active in the area of organ donation and transplantation and they are considering – and take

this as non-official information – to organise some initiatives next year on organ donation and transplantation, which I think could be a very good idea.

**Q29 Chairman:** What about the Muslim states? Are there more problems and less donation in Eastern Europe because of some of the issues around cultural and religious beliefs?

*Dr Fernandez-Zincke:* We have tried to record some experiences of some Member States regarding Muslim populations. For example, I think in Spain and also in the Netherlands they have some experiences on how to promote donations in these populations. As far as I know, there is nothing in Islam against organ donation.

**Q30 Chairman:** It is knowledge.

*Dr Fernandez-Zincke:* In most of the practice I think there is not any official statement of the church, let us say, promoting this situation, as it is in the Catholic Church. I think that this kind of campaign or initiative focused on these ethnic groups or on these religious groups should be promoted. It is one of the ideas that we are thinking to incorporate in this action plan, trying to find best practice in different Member States and previous experience, and trying to share it then with other Member States.

**Q31 Lord Lea of Crondall:** Have you ever heard it advanced within any faith group that there may be some preference for stipulating that an organ can only go to somebody else in the faith group?

*Dr Fernandez-Zincke:* I have to say that this has not only happened on the specific ethnic group. Some persons come to the transplantation services saying, “Okay, I want my organ for this specific population, this specific country” et cetera. What it is important in the allocation rules in Member States is that you are not able to select to whom you are going to donate your

organs because it is a gift, and it is a gift given to society. This element of equity should be maintained.

**Q32 Lord Lea of Crondall:** Other religious groups, as far as you know, go along with that.

*Dr Fernandez-Zincke:* I would not be able to give you this information.

**Q33 Baroness Neuberger:** When you said it is a question of education and particularly encouragement in particular groups, the issue that worries certainly relatively orthodox Muslims and Jews and which I think has been an issue for some Catholics as well is the definition of death. It is brain-stem death versus the cessation of breathing, and the definition of death being when somebody has stopped breathing for eight minutes which is often too late for taking some of the organs. I think there is a real issue and I wondered how much the EU is really taking that on and looking at the question about how you encourage ethnic groups and religious groups across the EU to make it as easy as possible to give organs, given the restraints.

*Dr Fernandez-Zincke:* I think that is a key element. Taking into account, for example, the data we have from Spain, nine per cent of the donors that they had last year were non-Spanish citizens, so were foreign citizens, and 50 per cent of this nine per cent were European citizens, so we could think that in the future more and more of our donor populations will probably come from donors coming from third countries and coming from different Member States. That is why this has triggered the need to go into these populations and explain it and try to promote donation. It was very useful when the Catholic Church made a clear statement about brain death. Then doubts disappeared, and I think that that has been pretty useful. If that could happen in other religions, that would also be very useful.

**Q34 Lord Trefgarne:** Brain-stem death will be the definition that is used.

*Dr Fernandez-Zincke:* Yes.

**Q35 Lord Wade of Chorlton:** What evidence can you describe to us, based on the experience of countries both inside and outside the EU, which sheds light on the benefits for the treatment of patients needing organs for transplantation that could potentially be achieved by improving the organ donation and transplantation services?

*Dr Fernandez-Zincke:* I would probably want to start with a sentence that I have heard sometime ago and I think it is very clear: I think that transplants are victims of their own success. If you go through the data, for example, we have already: a renal transplant recipient who has been living with their kidney for 43 years, and it is 33 years for a liver transplant recipient; 27 years for a heart transplant recipient; 24 years for a pancreatic transplant recipient. You can see that the long-term survival of the transplants have really increased in the last decade. Also, if you go through all the data of survival rates – and I am not going to bombard you with all the data I have here – the survival and quality of life of these recipients who have received a transplant has improved a lot in the last decade and that has provoked that more and more patients and more and more clinical indications are considered now for being on the waiting list for being the subject of transplant. That is probably one of the reasons why waiting lists have been increasing, but, even increasing the donation rate in some Member States, we cannot cope with the demand for transplants. There is another element here that it is probably not the most important – the most important is this improvement of quality of life and survival – and that is the cost-effectiveness. The studies that I have revised during the last years show that really organ transplants are a very cost-effective treatment. If you compare a kidney transplant, for example, with dialysis, dialysis costs six times more than a kidney transplant, so all the studies show that investment in organ procurement, in increasing organ donation rates, is, at the end of the day, a saving for the health system. Knowing that we have very good treatment and knowing that in terms of public health it is a

very cost-effective treatment, I think that it is another reason to try to promote this type of medical treatment.

**Q36 Lord Wade of Chorlton:** Thank you. What is your view of the problems posed by the European Working Time Directive for medical practitioners who need to work sufficient continuous hours in order to see through, from the beginning to the end, an episode of organ transplantation?

*Dr Fernandez-Zincke:* I can probably only give a partial answer to this question because it is not my direct competence. It is my colleagues in DG-Employment who are dealing actually with the Working Time Directive. I can say that the Commission has already incorporated a number of measures to this Directive in order to make more flexible this Directive in the field of health. Discussions are currently taking place in the Council and we will have a solution by December this year. So far, that is all I can say.

**Chairman:** You may be interested to know that this Committee produced a report on the Working Time Directive which would be very supportive of making it more sensible. Our country has tried to press that, along with, I know, a number of other Member States. It is an important issue.

**Lord Lea of Crondall:** Could I add a supplementary and declare an interest. I had something to do with the creation of the Working Time Directive years ago and the junior hospital doctors in this country had to fight for years to get some prejudices within the profession addressed. They had to work ridiculously long hours and the idea – and I am putting it to you to comment on that – that there are no downsides to doctors working until they are exhausted and almost fainting on the job is ridiculous. We have to see some balance in this and I am sure that that is in your mind. Would you like to comment on the problems of balance within Working Time and genuine worries?

**Chairman:** Lord Lea, I think this witness just said this is not his area of expertise and we may have an opportunity to ask someone else. The question is that these procedures do take this length of time, and, in order to get these operations seen through, that is what we are looking for in the balance. I think that is the point you were making, was it?

**Lord Lea of Crondall:** But does it have to be the same person hands-on all the time? That is a *non sequitur*, I would have thought.

**Chairman:** Sometimes cases have to be seen through.

**Baroness Neuberger:** One person has to be in charge.

**Chairman:** That is the evidence that has been given.

**Lord Wade of Chorlton:** I do not know the answer, not being a medical person, but how long might one of these operations take? How long does it take to do a heart transplant?

**Chairman:** Our specialist adviser informs me that it varies. Especially with a non heart-beating donor, from the identification of the donor, from the withdrawal of the treatment to the donor dying, it can go over days.

**Baroness Neuberger:** The view would be, from most of the doctors I know in this country who are involved with it, that they may not have to be there absolutely all the time but they need to be on call all the time because there is a time when you have to get up and do it. That is the problem.

**Q37 Chairman:** That is the problem about Directive, about the continuation. That is what we looked at when we did the inquiry. I have one last question about research and information, which I am sure you think is an absolutely crucial area. We are interested in knowing what proposals the Commission have for promoting and funding new research and improvements of information, in order to provide a sounder basis for organ donation and transplantation activities.

*Dr Fernandez-Zincke:* Thank you, my Lord Chairman. The European Union is already supporting collaborative research in a number of areas. I have a list of areas that very kindly our colleagues of the EU research have provided to me: immune tolerance to avoid/reduce the need for immune suppressive drugs; regenerative medicine approach, notably cell transplantation to regenerate diseased or injured organs; artificial organs; xenotransplantation; and identification of best practice, organisation of services, et cetera, at the level of the Health Service system. I also want to mention that the Research Directorate-General, in the sixth framework programme, has financed a project called ALLIANCE-O. ALLIANCE-O is a project that was looking into different research programmes on transplantation in the different Member States, for example, UK transplant was present in partnership, and trying to, let us say, approximate and coordinate these transplant programmes. The project has issued a number of conclusions that I can provide to you if that could be of any use.

**Q38 Chairman:** Also, what might be useful is where you think the gaps might be, where we need more information and research.

*Dr Fernandez-Zincke:* One of the gaps of transplantation research at Community level is that it is very fragmented. There are different research groups working in different Member States and there is not always effective coordination. One of the conclusions of this project shows that it is very important to try to have coordination of the research programmes at a national level. At the moment, few Member States have this kind of organism doing this job, to organise and coordinate the different efforts of different transplant groups. From the Community perspective, we have already funded a number of important projects in the last years. I want to mention the project of DOPKI, which is looking into methodologies to increase organ donation and mainly to see how the level of risk in the use of what we call “expanded donors” or donors who are not, in principle, ideal candidates. Also, the project Riset is a project that consists of researching into reprogramming the immune system in

order to avoid as far as possible the rejection of the organ. The DG Information Society has also funded a project on Eurodonor and EURO CET, which is a platform in order to inform the public about issues relating to organ transplantation and also trying to make a register of activities of organ transplantation and tissues and cells transplantation at the European level. Just to finalise: our Public Health Directorate is funding two other projects. The first one is on the training of professionals and the training of donor coordinators, and the second one is on living donation, trying to see what the different practices of living donations are around the European Union in order to try to establish guidelines for living donation programmes.

**Q39 Lord Lea of Crondall:** Chairman, I would like to add something to what was said earlier, a bit of supplementary information. It was news to me, but I think the speaker said that Spain was a net importer of organs, that Spain had more organs coming into Spain than went out. Did you say that?

*Dr Fernandez-Zincke:* No, no.

**Q40 Lord Lea of Crondall:** I am sorry.

*Dr Fernandez-Zincke:* On the contrary, there is a few exchange of organs from Spain and other third countries. I said that, from all the donors that are, let us say, in the hospitals in Spain, nine per cent of these donors are coming from other Member States or from other countries. It is not the organ which goes to Spain, it is the donor who is living in Spain or who is resident in Spain and who decides to be a donor in Spain. My point is that more and more in our populations we will have a higher percentage of foreign population living with us, and this population will increasingly be more important for the donor programme.

**Q41 Chairman:** The important message I took from that is that the structure of the way you do it is more important than all the other issues: if you get the structure right in terms of the

way you manage organ donation, you will get more people coming forward. That is something we need to take on pretty strongly in terms of our inquiry. It is 11 o'clock. We are extraordinarily grateful to you. I know the Committee have found that very informative and I have found it absolutely fascinating. We are sorry we have to rush through at such a pace but that is the way these committees do work. I think we have an extraordinary amount of information from you. If there is anything you think we have not heard that we should have heard, please do let us know. If there is any other question we want to ask you, I am sure you would be only too delighted to correspond with us if that was needed. Thank you very much indeed.

***Dr Fernandez-Zincke:*** Thank you very much, on behalf of the Commission, for giving us the opportunity to be here today.