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TAKEN BEFORE
THE SELECT COMMITTEE ON THE EUROPEAN UNION
(SUB-COMMITTEE G)

**INQUIRY INTO THE EUROPEAN COMMISSION'S PROPOSED DIRECTIVE ON
THE APPLICATION OF PATIENTS' RIGHTS IN CROSS-BORDER HEALTHCARE**

THURSDAY 30 OCTOBER 2008

RT HON DAWN PRIMAROLO MP, MR PAUL WHITBOURN
and MR JONATHAN MOGFORD

Evidence heard in Public

Questions 34 - 99

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THURSDAY 30 OCTOBER 2008

Present

Eames, L
Gale, B
Howarth of Breckland, B (Chairman)
Kirkwood of Kirkhope, L
Lea of Crondall, L
Neuberger, B
Perry of Southwark, B
Trefgarne, L

Memorandum submitted by the Department of Health

Examination of Witnesses

Witnesses: **Rt Hon Dawn Primarolo**, a Member of the House of Commons, Minister of State, **Mr Paul Whitbourn**, Head of Competition and Registration Policy, and **Mr Jonathan Mogford**, Head of European Affairs, Department of Health, examined.

Q34 Chairman: Minister, can I say how grateful we are that you are taking the time to speak to us on what we think is an extraordinarily important issue on cross-border healthcare. You know that your predecessor Rosie Winterton came to talk to us on the subject in January and we may or may not refer to some of the things she said in the course of the discussion. You are welcome to send us supplementary evidence after the session if you so wish. We already have quite detailed written evidence from you. When you start, could you give your official name and title for the record. Would you now like to make an opening statement?

Ms Primarolo: Thank you very much. My name is Dawn Primarolo and I am the Minister of State for Public Health. I am accompanied this morning by two of my officials who I will introduce: Jonathan Mogford, who is Head of the European Affairs in the Department of Health, and Paul Winterbourn, who is Head of Registration and Competition. His title has in fact changed, but that was the one that was provided to the Committee. I would be grateful if

I could make a few opening remarks before we turn to the questioning. I want to start by saying that I really welcome the opportunity to have this discussion with you this morning. The evidence from this inquiry will be very important in how we take forward our considerations on the draft Directive. As you will know, the draft Directive was issued in July and its main rationale – a point to which we will keep returning – is to codify ten years of European Court of Justice case law. The case law has established that patients have, under the freedom of the single market, a general entitlement to seek healthcare in another Member State at the expense of their home state. The issue of patient mobility is not a new one: there are longstanding rules under the regulation commonly known as 1408/71 that allow patients to access cross-border healthcare under the European freedom of movement, and, since 1998, case law has also been developed to allow patients access to cross-border care under Article 49; that is, the freedom to obtain services. Obviously the impact of these routes on the NHS to date has not been significant. I will not go into that now, because I know you will want to explore it, but the court has established that patients are only entitled to reimbursement of healthcare that their home system provides. The home health system only has to pay for the equivalent costs of treatment in the home health system. The health system can require patients to ask for permission before going. Thus far, the court has held that this can be justified for services delivered in hospitals. Where patients need to ask for permission, the court has said that permission must be given if the home health system cannot provide the service in a clinically justified time frame. The Committee will also be aware that we have the *Watts* case, in which clear case law has now been established for the NHS, and that has given rise to a number of ambiguities. I know we will come to those as well, so I am putting those aside. It is important, of course, that patients know where they stand, and it is also important that the NHS has clear guidance on their duties and also how health systems can manage the impact of patient mobility. For that reason, the Government welcome the draft

Directive as a means of codifying the situation in which we are already expected to operate. We believe that establishing a framework for patient mobility through the political process is preferable to continuation of case law varying entitlements that then we can never be clear on. Our first point is absolutely the draft Directive has to set high level rules on patient mobility that codify the case law. There are a number of helpful principles that we already have. The draft Directive acknowledges that it is Member States who run their health services. The second is that it is for Member States to determine what healthcare they fund. The fact that Member States control entitlement is absolutely a key point for the UK. The third is that Member States should only be required to reimburse treatment obtained in another Member State up to the level that they would have paid if they had treated the patient at home or the cost if it is lower. The fourth point – a very important one – is the helpful recognition that Member States can maintain referral routes – which we call gatekeeper routes – in their health systems. That, for us, is, for example, the requirement in the NHS that a patient is assessed by a GP first, before referral into specialist care. These are helpful though important principles, but that is not to say that the text does not need further amendment, and it does. We also want to clarify the scope of what is proposed, particularly where the Directive suggests that committees will be established to develop implementation measures, and, ultimately, I want to ensure that the text allows for the development of patient mobility in a sustainable way, that balances patients' rights with responsibilities, and – it is a very important and – allows Member States the flexibility to manage their health services. That is where we are at the beginning of a complex process. I have tried to lay out the principles that I will seek to pursue, building on the work of my predecessors in this negotiation.

Q35 Chairman: Thank you very much, Minister. You have set out very clearly some of the conflicts, if you like, that there are between the principles and we want to explore some of those. You have also set out, and I am not going to repeat it, the issue of where this all comes

from in terms of the need to codify. I certainly understand a little more why you are saying that the Government are now welcoming the Directive, and that was not necessarily so when we saw your predecessor. There is a greater clarity maybe about where you are going to. That being said, the issue we would like to start with is the level of demand you consider there to be in the UK for access to healthcare in other EU countries. We wondered in what circumstances this sort of service had been sought previously. What specific problems have arisen in the UK as a result of the present uncertainty in respect of EU citizens' rights to obtain such cross-border healthcare and have the costs reimbursed by the Member State where they reside?

Ms Primarolo: Perhaps I could start with demand and what we are seeing operating. Clearly there is already movement. We have – and I always forget what it is called – what used to be called the E111 (as those of us who are older will remember) for general travel in Europe. Then there is the E112, the 1408, which has existed since about 1972. We are already seeing some movement, and we are doing our best, but it is not significant. I will first give you some examples of where we think there may be demand, and we refer to this in our partial impact assessment. We can see that in the year 2007 approximately 550 patients were authorised to travel under the current arrangements encompassed in E112 – and I will come back in a minute to some further breakdown I have been able to get about where they are going and what for, although it is not totally conclusive. That number is quite small and we have the figures for previous years as well. We can also see that where the Health Service in the past has provided for arrangements for patients to choose to go outside of the UK with the treatment reimbursed, the take-up has been very low. I would refer you to the London Patient Choice Scheme which was run between 2002 and 2005. We were looking there at patients who had waited longer than we would have liked them to – if I might put it delicately. They were offered the opportunity, through the fact that we had contracts with other hospitals in the

European Union, I think primarily Belgium, to go and have their treatment faster there. The take-up was very low. That is showing us what we also see in patients' comments on satisfaction or criticism of the NHS, that the overwhelming majority prefer to be treated close to home. I think we can understand why that would be the case – and I was going to say particularly for the elderly, but that is true for all of us – because of family, recuperation, whatever. In that whole scheme we only saw about 1,000 patients – and remember we were actively trying to select. That scheme was closed down in March 2005, because there was such a low take-up. There was also a closer scheme, I think in the Kent area, where there was the possibility of crossing the Channel. Again, that was not taken up. We also see – and they are not big figures in terms of how many we treat – that the international passenger survey shows us there are 50,000 people who say they are travelling for health reasons. We can absolutely understand that health reasons would be a very wide definition when we are just asked to say, and therefore our consultation document is trying to tease out, first of all, how many people are travelling, and, also, whether more would – whether there is a knowledge gap – if it was clearer, and what for. The last point, which we have only just recently received, is what people are travelling for now. We find that between January and September 2008 there were 596 applications granted, of which 561 were maternity cases. Also, 402 of the 596 patients were travelling to only two countries: France and Poland. Although we would need more work, I wonder whether that might be a reflection of young people working here from those countries but young women wishing to return to be closer to, primarily, her mother and the wider family network when she gives birth; so, for instance, in that period 108 of the applications were to France and 294 were to Poland. I do not want to put too much on that because we cannot get any deeper into those figures.

Q36 Chairman: It is very interesting when you look at why people are travelling.

Ms Primarolo: Indeed. I have the breakdown and I will make it available. I only received it myself last night. If we look to 2007, again we see a similar pattern. There were 552 applications granted and over half of those were travelling to France or Poland. Again, interestingly enough, maternity. We cannot break down the 2008 figures yet, but for 2007 we see that, of all the cases travelling to France, 182, 128 were for maternity and 54 were for specific treatments, which we will need to get into. To Poland there were 105 for maternity and one for specific treatment. That is the best we have at the moment.

Q37 Chairman: Minister, in relation to that, do we have any other information that tells us whether these were UK nationals or whether they were nationals from these other countries, as you said, returning home? Because that is the significant issue, is it not?

Ms Primarolo: Absolutely. That was the crucial question that I asked. But we do not ask, for various reasons of non discrimination, the nationality of the person who is travelling. We establish their entitlement to NHS treatment. I have asked a number of times how I could get some indication and, regrettably, it is not possible. The numbers are quite small at the moment., but part of the consultation and further work that we will try to do is to work that out. I think it is significant that for both French and Polish nationalities, particularly young men and women who are coming here to work, that may be an indication. I really need to be cautious how I put that, however, because I do not know.

Q38 Chairman: Lord Trefgarne wants to come in, but I just want to comment that that has a wider European implication for healthcare, does it not, if that is the way people are travelling? I think we need to conceptualise that.

Ms Primarolo: Yes, it shows the importance of families, does it not? Very much, perhaps.

Q39 Lord Trefgarne: With regard to their nationalities, I should have thought their names would have been a bit of a clue.

Ms Primarolo: Yes – unless they married while they were here.

Q40 Lord Trefgarne: That was not the question I wanted to ask. I wanted to ask whether any of these figures include dentistry. There has been some publicity recently of dental firms going to some extent to attract dental patients over to Poland.

Ms Primarolo: We are trying to get more detailed questions with regard to whether people are travelling for dentistry and what type of dentistry; that is, whether it is what would be considered cosmetic dentistry here and therefore they would be in the private sector provision anyway, as opposed to the National Health Service. The figures are very small and it is difficult to tell. For instance, the number travelling, as I say, to Poland outside of maternity was only one. If we look at Spain in 2007, there were 25 maternity and 12 others for specific treatments. Regrettably, I cannot give you that information now but I am trying to get it. I do think it is relevant and I will make ----

Q41 Lord Trefgarne: It sounds as if your figures do not include dentistry, if there was only one.

Ms Primarolo: I do not think so. I think it may be because they are travelling privately. That is obviously relevant to the Directive.

Q42 Chairman: We are going to come on to that.

Ms Primarolo: Okay.

Chairman: Lord Lea is going to come in.

Q43 Lord Lea of Crondall: There is a reciprocal leg of the question, Minister, which you have not touched on, which is people coming this way. Do you have any numbers on that?

Ms Primarolo: No. At the moment I do not have numbers with regard to the number of people we are treating here through that scheme. The only numbers I have are the wider headline figures about the reimbursements that go on between Member States in treating each other's nationals. That is very complicated, because it is to do with retirement living abroad, as well as work.

Q44 Chairman: We are going to come on to ask you a little later about the implications for that.

Ms Primarolo: But we are going to try to see – and that is what the consultation is – because it would be decided at PCT level or at Trust level whether they took those patients.

Q45 Lord Eames: Minister, you touched on some of this in your introductory remarks, but I wonder if you could say something more to us about the rights to be reimbursed. The proposed EU Directive is already indicating that it is going to move to clarity on this. What clarity do you think the UK should seek? I am particularly interested in whether you think this applies to private medical care. It is really the area that you have glanced at in your introduction on the rights to be reimbursed.

Ms Primarolo: We have two separate mechanisms operating here and it is very important to keep both of those in focus. The first one is establishing the right to treatment. Article 6 deals clearly with that. Article 6(3) is very important for the UK in terms of making it clear that it is helpful language, because we are trying to make sure that it protects the NHS referral system, which is that a health professional determines the clinical need of the patient and determines then the treatment. That is part of how it would operate for us. The prior authorisation is about treatments already established and to which the individual is entitled, whether or not they apply to be treated in another Member State and at what level.

Q46 Lord Eames: Does this provide sufficient safeguards in terms of the dimensions that a patient is entitled to?

Ms Primarolo: We are of the view at this stage that the continued principles and keeping them – and they are buttressed at different points and in different ways in the draft Directive – so that the Member States determine their healthcare systems, the Member States determine what is available in their healthcare systems individually, and, then, within the structures of their health systems they have ways of determining your access to treatment: clinical need and then treatment. The question of prior authorisation raises a different set of questions. What would trigger that? The application is the trigger for considering prior authorisation. The prior authorisation is given for treatment that would have been available, that has been clinically determined at the tariff that is determined here, or, if it is less, that is what we pay. How will the prior authorisation will work? We think it is consulting on it, but I am of the view that that would be determined at the PCT, at the clinical level, because the patient and the clinicians will know what is best for them. The Directive, at the moment, says that it will be a reimbursement – and we start drifting into some other articles here, so I will try not to – so we need to look at how that would work. We have two levels of equity working here as well: the equity of the entire health system for everyone but then the individual. The steps in prior authorisation need to be clear, therefore, and to give clear rights, so that the patient knows what they are entitled to, so that the Health Service knows what it is giving, but there will be other things that we have determined. The patient needs to be absolutely clear who is responsible for giving the advice, which legal framework applies, what their entitlements are to after-care.

Q47 Lord Eames: Do you think we can achieve that clarity?

Ms Primarolo: Yes.

Q48 Lord Eames: It sounds so complicated.

Ms Primarolo: It is complicated. The principle is to codify the case law that we have now and not to open up any other areas, and not to leave, if we possibly can, any legal uncertainties or lack of clarity whereby the European court may have to determine something else in the future. I know that some of my colleagues in other Member States are very tempted, as always, and some of the professions here are, to clip other things onto this draft Directive, but I think we need to stay very, very focused. This system already operates in the UK because of the *Watts* case, but it would be very, very helpful to be clear on it.

Q49 Lord Eames: Finally, the private medical sector.

Ms Primarolo: As far as we can tell it is going to apply to private insurance. That is why we are consulting on this and speaking with the private insurance industry. One of the issues it raises is that we would have to have some awareness of – how can I put this? – insurance products that do not exist at the present time that might then be created that would have a backlash against the NHS or anybody else. We are experiencing this in the financial sector at the moment. That is an area. That is why the consultation is so broad, because we need to get to these and be clear. This is very, very early days on the Directive.

Q50 Chairman: We will be calling some of them as witnesses.

Ms Primarolo: Good. I have a feeling I will be back in front of you because this is going to go on for a while.

Q51 Lord Eames: I have a feeling the phrase is “You are very glad I asked that question”.

Ms Primarolo: Yes. Thank you. I am, indeed.

Chairman: We are going to have to move on. Lord Trefgarne, you want to pursue this legal basis.

Q52 Lord Trefgarne: Yes. Minister, you have already touched on the various legal provisions which apparently empower the Commission to do all this. The Commission are, of course, past masters at picking up a legal authority to do with this or that. Sometimes that is a good thing, and maybe it is in some aspects of this, but there is still the principle of subsidiarity; in other words, are we sure that they are not doing or seeking to do things on a Community-wide or Union-wide basis which we could do better ourselves and which the individual Member States could do better themselves? Are you satisfied that the Commission have the right legal basis for all this? You are aware, I am sure, that there were some Danish concerns expressed on this matter which might have pointed in the other direction.

Ms Primarolo: Clearly we know there is a tension in the Treaty between fundamental principles and the question of healthcare systems being determined by Member States. I want to be as clear as I can be with the advice that is given to me, that we must not lead to a risk of further legal challenge in anything that we do in this area. The advice to me is that we are using the correct legal base for negotiation here, but – and this is not unknown in long negotiations on Directives – sometimes that legal base can shift. We are staying very alive to that issue and discussing it with other Member States. The issue for me – and it comes up later and you might want to return to it at that point – is about what is meant by these committees and why do we need them if it is Member State determined. If we are codifying case law as it already exists – which is my view, that that is the only reason for doing this – why would we need that? I think there is always the danger that either inadvertently or by design it goes further than we intended, and all I can do on that basis is obviously draw on the expertise of those in this House and in the Commons, the evidence that I get. The NHS, as a health system within the European Union, we know is unique, but actually it needs to be protected, as it is not about bringing things into the NHS or making the NHS accountable to

anyone else except for the citizens of this country via the democratically elected representatives.

Q53 Lord Trefgarne: But it would be open to this Committee, would it not, if we were so minded and we were concerned that they were going beyond their competence or were attaching things, like the committees to which you have referred, which did not seem necessary to achieve what they were proposing, to say so in our report.?

Ms Primarolo: Yes, and I would welcome that. I fully appreciate, as you do, that this is very complex. If this Committee had a view on that, I would want to know it and to be able to take account of it.

Q54 Lord Trefgarne: Whether the Committee have views or not remains to be seen!

Ms Primarolo: Forgive me, but all views are gratefully accepted in the melting pot of working out how to achieve this.

Chairman: We will find a way of conveying our views clearly on this. You have been answering extremely fully and helpfully, which means it is very clear, and it means you have answered some bits of the question. The Committee will be aware of that. Lady Neuberger is going to take those areas of prior authorisation that you have not yet covered, so she will probably not ask the question in the form you will have had it, but I do not think that will worry you. Then she will go straight on to equity and we will come back to Lady Perry.

Q55 Baroness Neuberger: Minister, I ought to declare an interest. I am a director of the Voluntary Health Insurance system in Ireland, which is a semi-state insurer in Ireland and so is absolutely relevant to this. You have covered most of the issues around prior authorisation but I have two questions. What is your view of the exclusion of non hospital care from this? – and of course you have already talked a little bit about dentistry. Second which I think is a

real issue – if prior authorisation operates very differently across the EU – and it might – what is the implication of inflow of patients into this country, amongst other things?

Ms Primarolo: The non-hospital care is not excluded. It is that the reading of the case law so far by the Commission is narrower than ours. I think the Commission's view is that they do not feel there is sufficient evidence to justify that they should move to this. To be honest, I think this is another one of the many that we need to be watching very carefully, but, ultimately, the most important point is that it is the Member State decides and how it is funded. We only need to look at some of the recent reports in comparing this across the European Union, either on mental health services or misuse of drugs, illicit drugs treatments, to see ----

Q56 Chairman: Or organ donation.

Ms Primarolo: Indeed. The whole concept of primary care. There is not a concept. You cannot define primary care clearly, it seems to me, across the whole ----

Q57 Baroness Neuberger: We do not even define it completely here.

Ms Primarolo: No, we do not. I think that is why the Commission is avoiding that. Given we have a long time – because when it will have its first reading, we will have a discussion as ministers at the December Health Council for the first time – I think we need to be very clear and keep an eye on this. I have forgotten the other question. I am so sorry.

Q58 Baroness Neuberger: It is about the implication of inflow into the UK. It could be good if money comes with, but ...

Ms Primarolo: It depends, does it not? The primary purpose of the NHS is to improve the healthcare for the citizens of the United Kingdom. First, it is difficult to work out what the inflow may be – and we are trying to get information now, although it is very, very difficult.

But, given that Member States will be determining the flow through prior authorisation, and other Member States have mentioned very clearly to me the concerns that they have for the capacity of their own health services if certain strategic health services suck everyone in, I think there is already a countervailing argument about Member States coming the other way and how this would be sustainable and reasonable.

Q59 Baroness Neuberger: Absolutely.

Ms Primarolo: As far as I am understanding the provisions at the moment, if you like the receiving Member State has to agree to take the patient.

Q60 Baroness Neuberger: Which they might do on transplants, for instance.

Ms Primarolo: We would want it to be set in the conditions about taking decisions on the capacity of whether we could accept that patient into a Trust. Obviously, once they have been accepted, their treatment has to operate on a non discriminatory basis within the Health Service. Emergencies do happen and people do not get treated quite as quickly as they wanted to. We are consulting on how we would make sure it is non discriminatory once they are in the system, but have a clear view about capacity, because our first duty is to the overwhelming majority and that is how we plan and manage the Health Service nationally. This is, of course, for all of the UK, so the devolved administrations are also part of this consultation. I speak regularly, and my officials speak very regularly, to their officials about their views on this. We just do not know. Every health system will think they are the best and we are going to pull in loads of people. I certainly feel that and I think we need to consider it.

Q61 Baroness Neuberger: I think it is going to be complicated. Can I move on to equity. One of the things that appears to be the case is that there will be a requirement for people who

are coming from other countries or going to other countries to pay for their treatment upfront and then claim reimbursement. All the evidence that we have had – virtually all, anyway – has said that this is really inequitable and that the people who do not have the resources to provide the money upfront are going to be stuck. We wondered what you felt about this and, also, about the patients who go to other countries, get the amount of money that was available in their own country for that treatment, and then top-up? How is that going to work? What is your view, particularly as we have debate on topping-up going on anyway?

Ms Primarolo: I will not be drawn, at the moment, into top-up, if you do not mind. First, the Member State is responsible for the payment of the treatment that they decide they are going to pay for their national to have in another Member State. We are planning to decide it on the basis of professional diagnosis, clinical requirement, treatment. I think there are two levels of equity working here and they are difficult to put together. The first is for the overwhelming number of patients who will stay in the NHS. We have to make sure that if we have patients travelling in – the points you were asking just now – that does not affect our capacity to offer them the treatment to which they are entitled. For those who do have prior authorisation and travel, there are then two issues, and they are issues now. One is: Is there a discrimination between those who can afford to pay upfront and those who cannot? What does that mean and what should we do about it? We have individual equity but then we have the equity of all of us, of our community. Travel is another issue. At the moment, we reimburse, and it works, but we are consulting and asking for views on this. Of course, on the other side, we have to be mindful who we would pay it to if we did pay it upfront. That takes in some very difficult areas of fraud and how we would be sure they would go. Then there is the question of subsequent complications when they are back in the UK. Of course, on what some people call the “rescue principle”, you are in the UK and we treat you regardless. I think we still need to do a lot of discussion around this point, because we could end up with only the

wealthy having rights to access and that clearly would not be acceptable. We would not want to deny them because we know the right has to be provided. It is provided now. I cannot give you a definitive answer. We are asking and I am concerned about how we would start issuing money to individuals before they have their treatment.

Q62 Chairman: We will continue to ask these questions.

Ms Primarolo: Yes. It is vital.

Chairman: Whether we come up with anything helpful, we will continue.

Q63 Lord Lea of Crondall: Minister, I can understand why it is very, very complex, but you have used the phrase a couple of times “States will determine the flow,” or words to that effect, and I can understand how we can determine the flow authorising payment outwards, but at the end of the question we are asking about a significant net inflow and I cannot quite follow the process of determining, in other words rationing in some way, or making decisions on the flow inwards. Either you have a system set up with criteria and then it is automaticity after that, or somebody is going to say case-by-case, “Yes, you can come”; “No, you can’t.” Could you comment more on the inward side of it. I do not see how you can determine a flow.

Ms Primarolo: Yes, that is a difficult issue, but the Member State receiving the patient can refuse to take the patient.

Q64 Lord Lea of Crondall: Without going to the ECJ?

Ms Primarolo: That is one of the things we need to get clear in the draft Directive negotiations, that in order to protect our own capacities we would have to have the ability to say, “We cannot take your patient, sorry, because all our resources are being used in treating our own and we have no spare.” It may need to be done on a case-by-case basis because it

would tend to be the specialist treatments. For instance, we have put a huge amount of effort into reducing treatment times for cancer, and speed from early detection through diagnosis into treatment. We could not have that being disrupted for everyone else by an inflow of people who wanted to use that service as well. That is one of the things, I am very clear – and I appreciate you are drawing me back to it – that we will need to establish in a better way in the draft Directive.

Chairman: We have another question about national structures that Lady Perry wants to ask.

Q65 Baroness Perry of Southwark: I think you have answered part of my question and the question from Lord Lea is very relevant to this. At the present moment, access to care is determined at a local level, not at a national level, and we have no national eligibility criteria at all. Do you think that Article 6 will require the NHS to adopt national eligibility criteria? What impact would this have locally? How would you plan to calculate and publicise the cost of care, as Article 6 requires?

Ms Primarolo: We do have eligibility for us inside the UK, in terms of it is determined by diagnosis, identification of clinical need, and treatment. There is already a mesh between setting the standards and the requirements for the NHS and then the local determination. We can see no reason, in determining people's access inside the UK, why that would be questioned. The European Union has no locus on telling health systems what their standards should be or what their criteria should be. We are not seeking to determine the criteria for Germany or France; their health systems determine that. The only interconnection is that if a patient has an entitlement to something in Germany and chooses to have the treatment via this mechanism in the UK, our consideration is one of are we going to take that patient on the point of capacity and ability to treat.

Q66 Baroness Perry of Southwark: You used the word “our”. Who would that our be? If somebody in Germany was referred by their own consultant to the UK, would there be any mechanism whereby the whole of the UK structure could be looked at, to say, “We couldn’t take him in Newcastle, but we might be able to take him in Hull” or something like that? Or would they have to apply to a specific consultant in a specific hospital? If that consultant said, “I’m sorry, the queue is already too long,” would they be able to be referred around, to say, “We’ve got vacancies elsewhere.” How would it work? Who would make that decision?

Ms Primarolo: The patient has already decided where they want to be treated and by whom., so they will specify. They will not come to the UK and say, “We have a cancer patient, where can you fit them in for rapid treatment across the UK?” It will come in as a specific request for a specific consultant in a specific hospital, who will determine whether they have the capacity to take that patient.

Q67 Baroness Perry of Southwark: And Article 6 does guarantee that it will be done that way.

Ms Primarolo: I believe so, but we will obviously need to make sure that it is absolutely clear. That is the important point about the referral pattern that will exist, and at what point it will enter the UK system, if it did, for a patient in another Member State. That happens now. People ask to come and be treated in particular hospitals. Our own patients do it in discussion with their GPs. That is why this idea of having a national requirement on eligibility or criteria is not necessary, because this draft Directive is about individuals not systems.

Q68 Chairman: In some specialisms it already happens, does it not, that there are exchanges?

Ms Primarolo: Yes.

Chairman: Minister, I am aware that the time is running on. I would remind the Committee of that because we do want to get through a lot of questions with you. This is extremely valuable. I am going to move on to Lord Kirkwood, because one of our key concerns is: How do they know?

Q69 Lord Kirkwood of Kirkhope: Indeed. Article 10 of the draft Directive talks about an obligation to provide information. Would you confirm that is merely on request. There is no obligation to promote any of this new service. I hope that is a yes or no answer.

Ms Primarolo: There is no obligation to promote it. I was looking for all the sites – I have a list of them – but, forgive me, I cannot find it. Because of the *Watts* case, there is already information and access via NHS references that individuals can access to know how they go about seeking prior authorisation to be treated somewhere else, but we are not obliged to promote it and we would not.

Q70 Lord Kirkwood of Kirkhope: That is all I need to know.

Ms Primarolo: I just want to be clear. We would not keep the patients' rights a secret from them, because that would not be permitted. They are entitled to know their rights, but it is not something where we will have posters up everywhere saying, "Would you like to go to France?" I am sure lots would, but not for treatment!

Q71 Lord Kirkwood of Kirkhope: Could I refer you very briefly to your written evidence, which is very helpful. In paragraph 18 you say, "Nevertheless, we have concerns about how much practical information about treatment options in other states the NHS will be able to provide." If we are talking about practical information, how on earth is the NHS expected to know what is happening in Luxembourg?

Ms Primarolo: That is the very big question and you are quite right to settle on it. This is my view and I would be interested to hear whether you think it is incorrect. If one of our citizens says that they want to go and be treated somewhere else and they are in the prior authorisation process, clearly we will want to provide as much information as we can to them of the risks as well as the opportunities: the risk that you are away from home and these health systems are not exactly the same as the UK; that you may not be spoken to in English all the time. That does raise the question of how much information, once an individual has asked to be referred somewhere else, we feel we can give them, and then how we convey to them what we are unable to tell them. Therefore, it is ultimately up to them. Also, they will have to give us permission to release their records, and I think we need to do that on consent, on an individual basis. Our ability to know what is going on somewhere else is going to be difficult, of course, and it will be incomplete, and we will have to convey that. I think we have a duty to do that. If you think not, please say. It will not be in the Directive, it is how we might try to apply it. There are not the same rights, there are not the same standards, there are not the same styles of treatment, there is not the same access to treatment.

Q72 Lord Kirkwood of Kirkhope: You can give us an assurance that this is something you are focused on and you are going to continue to keep up the pressure to try to get a better understanding of exactly what is expected of Member States in this new system.

Ms Primarolo: Yes. And what is not expected of them because it is not deliverable. You can have headline messages that look very sensible, but they are absolutely not deliverable and we need to avoid those.

Q73 Lord Kirkwood of Kirkhope: That is very helpful. You might be able to help us with notes on these two things. The Committee would like to have a better understanding of what the Commission are talking about when they refer to a “standard Community format”. I do

not know what that would look like. Does the department have an understanding of what it is supposed to provide and what it would look like and whether we would be in favour of it? I have a second point in terms of national contact points. I have looked at the papers and I have only a very vague understanding of what the Commission have in mind with these things. With the exigency of time facing us, it may be that a note to the Committee would suffice, but maybe you could deal with it very briefly in the evidence this morning or take it away and send us a note.

Ms Primarolo: Are you referring here to the question of the issue of prescriptions, the e-health -----

Lord Kirkwood of Kirkhope: No, my understanding is that it is only in relation to the provision of information.

Q74 Chairman: Could I ask that the Minister is allowed to take this away, in view of the time, as you suggest. Maybe your officials could let us have a note on this.

Ms Primarolo: Yes.

Chairman: That would give us an opportunity to move on.

Lord Kirkwood of Kirkhope: It is just clarification. I do not know how difficult it is, but it would be very helpful to get it clarified.

Q75 Chairman: Thank you very much. Of course all this takes us straight on to this question of liability and redress, the question of what information they should have, what our expectations are, and what happens to them when they get there. To what extent are you content that the UK meets these requirements already? How content are you with the UK system of discretionary indemnity? – and we have to say that we have had critical evidence about that. Could you explain what you are referring to in paragraph 18 of your evidence when you state that, “Patients will need to ensure they have adequate insurance arrangements

to cover their treatment”? That sounds like a straightforward sentence but you can understand why it needs unpacking.

Ms Primarolo: Nothing is straightforward here.

Q76 Chairman: If all Member States apply Article 5(1)(d) and (e), surely there should not be a need for such insurance.

Ms Primarolo: There are differences. The NHS has a system for complaints and then we have liability requirements. These are not the same across all of the European Union. In particular, in the UK, when items become actionable for neglect or harm that leads to compensation. Our view is that Article 5 is not clear enough with regards to how complaints, liability, negligence fit together. We do know – and this comes back to the point I was making about information to patients – that the patient will be within the liability and the legal framework of the Member State in which they are treated. They will not be within the UK. It does not follow them. Therefore, it may be that they will not have as much from cover for those items as in the UK. We need to try to be clear on the limits, so that people at least are aware and have the opportunity, if they wish to, to insure themselves further in those circumstances. Because they are not in the UK system in Germany.

Q77 Chairman: I can hear the patient saying, “But this consultant gave me the information and I then went to this country where things went seriously wrong. What is the liability of my consultant who suggested I should go?” Is that where we need the clarity here?

Ms Primarolo: We need the clarity that this is not a referral. The consultant will need to be very clear on that. It is an individual’s choice to exercise a right to access outside the UK. We are not providing for new rights – coming back to what maybe Lord Kirkwood was trying to get to. This draft Directive does not provide new rights; it codifies what already operates.

We are not creating a European-wide health service whereby consultants can decide to refer somebody somewhere else.

Q78 Chairman: I think in your earlier evidence you said that a clinician would have to agree that the treatment was necessary and that the clinician who was going to receive was an appropriate clinician. I am only seeking the clarification which I think is what you are really looking for in the Directive.

Ms Primarolo: There are two separate issues here. One is that the treatment that is determined is determined within the United Kingdom framework. All of us are treated exactly the same, and that is how we reach the point where you have clinical need and what your treatment is. It is entirely separate – but important for us, because of the way our health system works – from the proposition that this draft Directive is seeking to provide for, which the case law provides for, which is that an individual can choose to receive payment and have that treatment somewhere else. It is an individual's choice. It is not about systems. It is not about referral. It is not about saying, "Here is a European-wide health service, I will take my money and go somewhere else," as inside the NHS. That is why these very difficult issues of insurance, standards, negligence, all the things that we have been talking about, need to be clarified. This is the first draft. The principles, as I said at the beginning, are okay, and we are happy with them – some we are not, and we are doing further negotiation – but even those principles we need to be clear exactly what it means. In terms of the additional requirement on indemnity, as I understand it the current framework for legislation has been put in place and does not apply in that sense because it reserves it for the Member State. I know there is some discussion around this and we will continue to look at that, but we think that is a separate issue. I am sorry I am giving a rather long answer, but it is very important that people understand that it is not referral and that members of the public understand this. They are making an individual choice and they take the responsibility for stepping outside the NHS.

We cannot do anything about that. If they come back and there are complications, without question we will pick that up – and that is something else we are going to have to sort out: we will not say, “No, you had that done somewhere else” – but there will need to be some clarification here.

Chairman: That is extremely helpful. It gives us some questions too to ask the people who are raising issues around this. Lady Gale is going to ask questions about language and after-care.

Q79 Baroness Gale: Good morning, Minister. I am going to ask about practical concerns, although I think most of us this morning have been dealing with practical matters as well, on after-care and language. In your evidence you acknowledge the practical impacts of the Directive and you consider that after-care should be the responsibility of the Member State of treatment but follow-up care could be provided by the Member State of affiliation. Are you seeking to clarify in the Directive where these responsibilities lie? As far as language is concerned, you say that the patient will need to make adequate arrangements “for addressing any language difficulties”. What level of obligation do you consider should fall on the patient to overcome any problems relating to language and what responsibility should lie with the medical provider?

Ms Primarolo: On the question of the immediate after-care, I think it is not unreasonable and we can all accept that immediate after-care comes to be done where you have had the treatment in the first place. That is what we would expect. But the draft Directive is not particularly clear and I also appreciate that working out the language around providing for that could be somewhat difficult. Where there is difficulty, it is in the consultation. That is why we are doing the consultation document in asking some questions around that issue of after-care. What do we mean by after-care? Immediately? What if you have something and your after-care is that you should be in intensive care? What if a few days after you need

intensive care because a complication develops? I would like greater clarity, I do not know how to get it. I think it is fraught with difficulty and that is why we are consulting on it. But at the moment I do not think it is unreasonable to say we would expect a certain proportion of that after-care to be located with the patient when they have the treatment in the first place. On the question of requirements for translators, the Health Service itself plans for that now. Again, it is in the consultation. But, personally, I am not minded to put this in as a blanket requirement. I can see the difficulties, but if we start from the proposition that an individual is making that choice, that is one of the issues maybe they would need to consider. It is working out this very difficult line of codifying what is a right now. I make no bones about it: I am intent on making sure – I would say this – the National Health Service is the best service. I want it protected. I do not want to leave it open to further legal challenge if I can avoid it, and I do not want to extend rights because capacity planning and delivering the service that the overwhelming number of citizens want close to home could be undermined by this. I suppose that you could say that I do not think we should provide a blanket requirement, but if somebody comes up with a really convincing case then of course I will look at it. But it is really important to understand that this is an individual choosing something. If an individual chooses to go private, we do not have all these things about what is the NHS going to do. They are stepping outside our system with the right to take the money.

Q80 Chairman: Minister, you have already given us over an hour. We are obviously finding this extremely useful. Are you happy to continue for another ten minutes or so?

Ms Primarolo: Yes, of course.

Q81 Chairman: We need to ask you that out of courtesy.

Ms Primarolo: I am happy to stay.

Q82 Baroness Gale: May I ask one question on the Minister's reply in terms of language. It could prevent someone seeking treatment, if the patient had to pay for translation facilities, because it could be quite expensive. If somebody from the UK was going to France, for example, and would have to provide their own translation facilities, or if people were coming into this country, surely that is going to limit the people who are coming because of that extra cost. If you cannot afford that, you cannot go for that treatment.

Ms Primarolo: Under the case law, the individual will be checking with a provider and maybe that is something they might like to ask. I feel just a little uneasy about using National Health Service money to provide additional services that we would not provide, on the basis that an individual has made that choice, when we know that across the budgets of the NHS we are always having to look at priorities and there is never enough money. I think it comes back to this – and in your deliberations you might consider this: What is the role of the individual? What is their responsibility in taking up this legal right that is provided? At the moment, I absolutely agree with you that it would be a cost but they would have to take that into consideration.

Q83 Chairman: We must move on. It is a tension between equity and rationing, is it not?

Ms Primarolo: It is indeed.

Q84 Chairman: Which is what we have perpetually.

Ms Primarolo: Well, equity and planning.

Q85 Lord Lea of Crondall: Minister: mutual recognition of qualifications. Obviously this has been going on for donkey's years. I remember, it must be 30 years ago, that the TUC helped the BMA find their way around Brussels. One of the big developments has been the professional qualifications system. Does this Directive bear on this or not? We have received

written evidence from the Nursing & Midwifery Council who say that the rules on recognition need clarifying. I am not very clear what they are saying there, but would you like to comment about whether this is totally, as it were, down to the professions or is there something that has a bearing on it in the discussion of the Directive?

Ms Primarolo: Article 11 says, “This article does not apply as far as recognition of professional qualifications is concerned.” I think that is quite clear. It comes back to the point I was making earlier on, that at the moment I am keen to keep outside of this draft Directive anything that is not directly relevant to codifying the case law. I have seen the evidence from the Nursing & Midwifery Council. The Directive on professional qualifications did bring together a number of Directives into a single Directive and, if you like, the transposition of that into UK law included a consultation process as well. The draft regulations amending Nursing & Midwifery Orders were drawn up in very close co-operation with them. I think that the general principle of healthcare in the draft Directive is that standards of Member States of treatment apply in their healthcare systems. That is quite clear and, therefore, I do not take a view. I think it is my job to be focused on making sure that inside the National Health Service we have high quality, safe health services. That is paramount in terms of our standards. We set the standards and the qualifications for us. This is one of the difficulties. Given that we are not creating a European-wide health service, because of subsidiarity, and quite clearly we are not, that happens when people step outside and the standards of that country apply. I hear the point and they have made it before. There are remedies and that is being taken forward, but I do not think, in my view, it is relevant to this Directive. I stand to be corrected, but that is my view.

Q86 Chairman: It for this Committee to be asking the question about standards within the Directive, I would have thought.

Ms Primarolo: Absolutely.

Q87 Chairman: Which is a different issue.

Ms Primarolo: Absolutely.

Chairman: Thank you very much indeed. That is helpful. Lady Perry is going to ask about co-operation between Member States.

Q88 Baroness Perry of Southwark: Minister, you said in your evidence that you have some concerns about co-operation between Member States. Could you expand on those, particularly in regard to the recognition of prescriptions issued in other Member States. To what extent might this impact upon the possibility of making a top-up payment for drugs that are not publicly funded?

Ms Primarolo: My view on co-operation is that, as long as we are clear what it is, it is a good idea. For instance, I co-operate and we have discussions on pandemics influenza, not only across the European Union but more widely. It is true that there is now the matter of prescriptions and being able to have a prescription from one Member State into another. We are consulting on templates, and, again, that is part of this, but they can be fraught, in that they then imply vast systems that make it very difficult to maintain the planning of the Member States' health systems. My view is that the European reference network, exploring and looking at e-health within certain arrangements, the technology assessment programme where we are sharing experience and information, are things that we can do, because we co-operate and we speak, but I do not want to see it moving into the main text of the draft Directive. I think it will open up areas that are not dealt with in the legal judgments, so there is a place, but we need to be clear on what that is.

Q89 Baroness Perry of Southwark: If a patient were to come back from France, let us say, clutching a discharge prescription for a drug which currently the NHS is not prepared to pay for in their PCT, what would the position be?

Q90 Chairman: You may be in some political difficulty in answering this question.

Ms Primarolo: I may be. In fact, I am. Could I come back and answer that question another time when I am able to be more frank with you. How could I put it? I think there is a way around this. I am sorry. Forgive me, but I think this should be one of the notes ----

Q91 Chairman: We do understand. This is an ongoing matter.

Ms Primarolo: -- when I am able perhaps to be a little clearer on whether we think that is a possibility.

Q92 Chairman: In the terminology: you will write to us.

Ms Primarolo: Yes. Thank you very much.

Q93 Chairman: We have a few minutes before half-past. You might wonder why I am asking the question about consultation and administration. That is because we are so well represented on this Committee: we have a Welsh, a Scottish and an Irish background member, and so the English member is asking the question. You say in your EM that you have consulted with the other administrations during the preparation and the discussion and we just wondered if you would tell us how that consultation has taken place and whether there has been a good response.

Ms Primarolo: There are the discussions that I have and the exchanges that I have had directly with the ministers in the devolved administrations. I am the English Health Minister but I sit on the Health Council. This draft Directive is for the whole of the UK, and so, particularly at official level, there has been a great deal of discussion and we have drawn on their views. We agree. I have correspondence, as you would expect, before embarking on this, from the ministers, saying that they agree with our negotiating position and the sort of points we have discussed this morning, and these are their fears as well. On the consultation

document – this is the consultation document going out across the United Kingdom – naturally, we have their agreement. There is not a separate consultation. The closing date for the consultation is 8 December, but that is running now. I will hear from them again, and we will then be discussing, before it is published, what the consultation says and what we might do next, so that we are all agreed.

Chairman: The Committee are keen to know what happens if there is a view in Scotland that is directly different from one of the other administrations?

Q94 Chairman: And I only take Scotland as an example.

Ms Primarolo: I am sure there will not be.

Q95 Baroness Gale: In EU consultations with the devolved nations – and I am thinking in particular about Wales – you have this consultation, you talk about it, and you come to a decision. Are these discussions within the devolved administrations made public? Could we have a look at them to see really what had happened in those discussions? If there were to be a disagreement, do you eventually resolve it, so that you have one view going?

Ms Primarolo: Actually, it has gone swimmingly. There having been discussions at official level, I then wrote to the ministers saying, “This is how I think we should try to manage these negotiations. Here are the headlines. What do you think?” They then took their officials’ advice. They replied back to me, saying that, yes, they agreed. They flag up any concerns they might have – I do not recollect any right now – because every minister is motivated by the operation of their health systems to the maximum benefit of the systems. On the consultation document there was an issue as to whether each administration would do their own consultation, and then it was agreed that might not get us some very good responses and we should all be asking the same thing. That was agreed. Whether I could release those private letters, I do not know. I would need to ask them. But I think I am right in saying that

we never resolved the conflict because there was not a conflict in how we should approach this development. If there was, we would have to sit down as ministers and find a consensus position.

Q96 Baroness Gale: It would not be the norm to release these letters. That is all I am asking.

Ms Primarolo: No. These are private exchanges between ministers. I have to say, they are not earth shattering, because we were in complete agreement. If the Committee really, really wanted to see them, I do not think it would shed very much light. It is, “Dear Edwina” and then a letter comes back, “Dear Dawn, Yes, I agree. We are concerned about this like you are.”

Q97 Chairman: It would not be admissible under the Data Protection Act, because it is ongoing work in a piece of work.

Ms Primarolo: It probably comes under policy, yes.

Q98 Chairman: Minister, I would normally ask the Committee if there are any more questions, but I am not going to do that for obvious reasons. You have supplied us with an absolutely excellent framework for us to move forward and you have given us room for many more questions that we will be able to ask. We note that there are one or two things on which you are going to come back to us and there are things on which we may well come back to you through your officials if we have further questions. Meanwhile, I am sure the whole Committee joins me in thanking you for an excellent session.

Ms Primarolo: Thank you very much. We will get the information to you as quickly as we can and of course my officials stand ready – or they do now! – to answer any further questions that might arise in your considerations.

Chairman: Thank you very much indeed.