

THURSDAY 13 NOVEMBER 2008

Present

Gale, B
Howarth of Breckland, B (Chairman)
Lea of Crondall, L
Morgan of Huyton, B
Neuberger, B
Perry of Southwark, B
Trefgarne, L
Wade of Chorlton, L
Young of Hornsey, B

**Memorandum submitted by the Patient Liaison Group of the Royal College of Surgeons
England**

Examination of Witness

Witness: **Ms Lesley Bentley**, Chairman, Patient Liaison Group of the Royal College of Surgeons England, examined.

Q142 Chairman: May I welcome you and thank you for taking the time to come and speak to us. If we do not get through everything and you do not think that you have said everything you want to say, you can send us supplementary evidence; but we already have your very useful evidence, for which we are grateful. Perhaps you would begin by stating your name for the public record, and you may then want to make a short opening statement.

Ms Bentley: My name is Lesley Bentley. I am lay Chair of the Patient Liaison Group of the Royal College of Surgeons of England. I would like to make a short statement, because patient groups vary tremendously in their structure and their role. It is just to clarify what you are actually going to get from me. The Patient Liaison Group works to bring patient concerns to the attention of the College and to provide lay input to its numerous policymaking committees. It is made up of 12 lay members and six surgeons. Most of the lay members are either patients or carers of a patient; they are volunteers who are non-medical; they do not

represent any organisation; their views are their own as individuals. The PLG therefore provides a collective lay view from individuals who bring a patient perspective to the College.

Q143 Chairman: We will go to the questions now. You will know that the draft legislation under examination is a direct result of the legal uncertainty in this area, which has already led to things like the *Watts* case being heard and the outcome of a number of issues in the European Court of Justice. That confirmed that costs incurred by a British citizen who sought treatment abroad due to a long waiting period in the UK should be reimbursed. We have that context, therefore. On the basis of the practical experience you have as a patient group, what is your view of the need for EU-level action in this area? What do you consider should be the key objectives of this proposal, and what do you think the implications of failure to agree any such legislation might be?

Ms Bentley: On the first point – on the basis of our practical experience and EU-level action – I have five points. First, fairness: that greater clarity is needed; otherwise there would not have been the court cases. Secondly it is very important to apply standards. Healthcare systems may vary between Member States. Thirdly the PLG has no direct experience of a volume of patients seeking treatment abroad. Our experience of patients is that patients want to have the highest quality of patient care and safety provided locally to them. That is our experience. Fourthly, based on our experience we have concerns that the sort of patient issues that arise in this country may well apply on a much larger scale in Europe as a result of this change. Things like effective communications, continuity of care and the efficient flow of crucial clinical information could all possibly be considerably worse, on a much larger, EU scale. That would be our concern. The fifth point is we believe that EU politicians must take responsibility for the possible increase in volumes of patients moving to take up this right. I believe that it is small at the moment. They must prepare adequately for this possible development. We feel that it is not enough to assume that the current levels of patient

demand will be the norm. That is on the EU level, therefore. On the second point, the key objectives, obviously standards of patient care and safety are crucial. The right of patients to seek treatment abroad must not compromise the right of others, who have decided to stay at home, to receive the highest standard of care at home – through hidden costs, workforce planning and other issues. The objectives must ensure clear information, so that patients can make those choices to seek to go abroad or not; and they must provide a clear procedure for redress if things go wrong. These objectives are addressed in the directive, but we feel that there are a number of other issues that are very important to patients that are not addressed by the directive. The first one is the definition of what is meant by “patient care” and the importance to patients of “pathways of care”. The treatment for many conditions involves a series of procedures and treatments not necessarily just one; delivered by a multidisciplinary team in constant communication; from diagnosis, through treatment, right through to social care and support once the patient gets home. I know from my own personal experience as a cancer patient that I was not aware of that. When I had my diagnosis, the first response of my family was “Who is the best surgeon? Where do we find them?”. I did not know about pathways of care but I wanted to be treated at home and, as it happened, I had a very good surgeon and I was treated in the NHS near home. As a patient, I realised the importance of that multidisciplinary team. They were working closely together right from the start. I was passed – to me, seamlessly – from one set of procedures and treatment to the next, right through until I was supported at home. The care and support I received from the district nurses was, to me as a patient, just as important as the care I received while I was in hospital. That happened because somebody was in overall charge, overseeing that. That is crucial. The important thing is that patients are not necessarily aware of that. They may think of treatment as discrete packages of care; therefore, when they are diagnosed they may think, “Ah, I will have that one” and go and get it abroad. Inadvertently, they may lose the strength

of the pathway of care - its continuity. The other important area in the pathway of care for patients is the continuity of caring and of personnel from whom they receive that treatment. It is very important for patients and has an impact on their outcome. I wonder if this directive and this right may distort that slightly. The patients may therefore lose the value of something they did not know they actually had. Pathways of care are therefore very important. The other issue is, if they do take a discrete piece of care overseas, how they then get back on the pathway when they get back. Another point is the issue of patient choice, which underlies the whole of this directive; but we are only just starting to look at this issue here from the patient point of view. It is a complex issue.

Q144 Chairman: If you do not allow the Committee to ask some more questions, you will take up all your time on your first question.

Ms Bentley: I apologise.

Chairman: It is fine, but I know that Lady Neuberger wants to follow up this question of information. If she talks with you about it, she will be able to tease out the things we really need to hear from you about information.

Q145 Baroness Neuberger: You have already raised the issue of information and what do patients know, and so on. The real issue for us here is whose responsibility is it to provide that information? What should it consist of? How do you make information available that makes it clear to patients? What will it contain?

Ms Bentley: This is a very difficult issue. It is not sorted here, and so how it would be sorted on an EU scale is a moot point. Having thought about it, we think that the EU is actually responsible for collecting and providing that information on an EU scale – in theory. I must stress that we are talking here as lay people. We do not have to do it. We are saying that this

would be an ideal situation. We are lucky enough that we do not have to implement these things necessarily!

Baroness Neuberger: You are asking quite a lot of the EU!

Q146 Lord Trefgarne: And the Commission.

Ms Bentley: It is EU-based information.

Q147 Baroness Neuberger: For our purposes as a Committee, you could argue that the information must be collected EU-wide. It would not necessarily mean that you would expect the Commission to provide it.

Ms Bentley: No, absolutely. However, the EU must take responsibility for the quality of that information. That is the main point from our point of view.

Q148 Baroness Neuberger: Or an EU body or somebody charged by the EU.

Ms Bentley: An EU body, so that there is some standard across Member States. If information is provided by the Member States as to what healthcare they provide as an option, it is important that there is some quality and standard put on that to make sure that information is valid and means what it says.

Q149 Baroness Neuberger: You also raised, I think importantly, this question about a national advertising campaign to raise awareness across borders. If this were to happen, who would organise that and who would pay for it?

Ms Bentley: Funding would obviously be very difficult. To some extent it will be up to the national states, given the difference in languages, et cetera – and they know the way to appeal to their local populations – to run a campaign. You can do it in other ways. For instance, most of the population watch soaps; they watch TV; the media is huge. You could put these scenarios into *The Archers* and *EastEnders* for example. If you did that, you would probably

reach far more of the population than if you ran a formal campaign. There are ways of doing it, therefore, which may not be overly expensive but you need to tap those roots where patients pick up their information.

Q150 Baroness Neuberger: If you do not do that, if there is not some kind of campaign, presumably your argument is that it just will not happen. Is that what you think? Or that it will happen badly?

Ms Bentley: There will be inequity, because those who are on the ball, who are on the internet, who find out these things, will go ahead and find out and they will make the best decision. Those who do not have that available will not know that that option is available and will not know how to make the choice.

Chairman: I would like to move on to equity, because this is an important issue. What you have said also raises issues about priorities. If you think that people need care nearer home and they spend money on getting it abroad, there are real issues of priority, which the patient groups might like to talk about. I will ask Lord Wade to plough on with equity.

Q151 Lord Wade of Chorlton: You have highlighted the issue of equity in your written submission, suggesting that those with more limited resources may require additional help in making the decision to access cross-border healthcare. What are your views on the equity of the proposed directive, and how well do you think the proposal addresses issues of equity, including the one you have highlighted and any other financial concerns?

Ms Bentley: I have to say that I found parts of this directive impenetrable. They read as a translation. It was difficult to understand in parts. The emphasis seemed to be on equity on financial terms; but from our point of view as patients there are far more issues than that. I feel that there will be those who, for whatever reason, will not feel able to take up this right. They may then be left with less choice, possibly from a poorer local service. There are huge

issues for patients. This right implies distance for us in the UK. To take up this right, you travel further. For lots of people it means that they will then be away from their family support, their community and all the other things that, when people are anxious and in hospital, are very important to them. Some people near where I live have refused treatment at a centre that is some miles away because it is out of their area. They have not made that decision on the best clinical basis for them; they have made it because they do not want to go out of their area and it would be difficult for them to do so. That is a real issue that needs to be addressed. There must be no compromise of the care that they have available at home if they choose not to take up that right. Payment upfront will be a real disincentive. It questions a fundamental principle of the NHS, which is that it is free at the point of need. There may be a fear by patients that this system of payment upfront could start to erode that important principle. The fact that you have to pay upfront will put off a lot of people who do not necessarily have the resources. It mentions in the directive that you will get reimbursement to the cost of that treatment at home, but it then says somewhere else that if there are additional costs you will meet those. I think that would put people off a great deal. The language issue would mean that it would put people off – just the fear of not being able to understand and therefore not wanting to go there.

Q152 Chairman: Lady Gale will pursue language later.

Ms Bentley: Also, social security. The other care, the home care ---

Chairman: Ms Bentley, you are giving us a lot of information very fast. I will ask Lady Gale to pursue language.

Q153 Baroness Gale: With 23 official languages in the European Union, and unofficial languages like Welsh in the UK, for example, any legislation on the provision of cross-border healthcare clearly needs to take the issue of language seriously, given its critical importance

for patient safety. Whose responsibility do you think it should be to address any language barrier, both in terms of arranging and funding any necessary provision for translation and interpretation?

Ms Bentley: It will again be an issue of what is ideal. We found this to be a really difficult issue and, as you say, this understanding has very important implications for patients. However, we felt that it would be asking the impossible for all hospitals in the EU to have on standby 23-plus translators or interpreters for any patient who might happen to turn up. We therefore said we felt that it was the patient's responsibility. We thought that it was the patient's responsibility to understand that there will be language issues, which in itself leads to huge problems of equity of access. We feel that this is a really difficult problem that we certainly are not happy about; but that was the only real conclusion we could come to on that. We did think that there was the possibility of voluntary organisations that have links in Europe – the Coeliac Society for instance – providing support, but that would apply only to those conditions covered by them. The point we want to make in all of this, however, is that effective communications are so much more than the linguistic aspect. We have problems in this country with people whose first language is English: doctors who are not getting their points over effectively and in a way that helps patients. You have only to look at the Medical Defence Union to see that many of their cases are because of communication skills. If you add linguistic skills to that, we would be really concerned about it. I believe that communication skills and their effectiveness can have a very important effect on the outcome for patients. I do not know how you resolve it. It is a very difficult area, but it is one that may pose extra problems for patient care and safety in an EU setting.

Q154 Baroness Gale: You see this as quite a problem.

Ms Bentley: Absolutely, and also for the information coming back. Say a patient has some treatment overseas and comes back onto the patient pathway in the UK, where they have to

pick up on treatment, it is crucial that the information fed back to doctors in the UK is understandable, clear, not misinterpreted and that it is received in a timely fashion. All of those issues will be very important to the outcome for a patient.

Q155 Lord Lea of Crondall: May I ask a brief supplementary? This spectre of 23 qualified people in every hospital in the European Union, hanging around in case somebody wanted to speak Albanian, is a caricature obviously. If you break your leg in one of these places, someone will fix it one way or the other. Somewhere between those two extreme caricatures, would you say that one has to talk a little more practically?

Ms Bentley: Yes, obviously. However, with all this, as it seems, you will find out what many of the issues are only once it is underway, and I do not know if that is the right way round. It may be that the flows of patients come only from certain Eastern European states to the UK, or the UK to Germany, or the flows may be fairly definable, in which case you could start to deploy resources. The other issue is that the home country may also have language issues. They may feel that they would like the priority to be for their population also to have interpreters to help them; and there could be a conflict there sometimes. Once it starts, you may well see that but is that the right way to find out what the problems are?

Chairman: Presumably the consultant who talks to you about where you are going to get the treatment will have some thoughts, and this takes us into prior authorisation and how all that happens. Lord Trefgarne wants to pursue the prior authorisation issue, which will have to do with the assessment of the situation.

Q156 Lord Trefgarne: I wanted to ask you about the pitfalls or maybe the advantages of prior authorisation. I can see the justification for it, but what is your view on it?

Ms Bentley: It is put in the directive as a barrier, potentially, to this right for the freedom to seek treatment and could be viewed that way. The draft directive emphasises the financial

aspect of it. There is also another extremely important aspect for patients. We feel that there should be some clinical input to the decision to seek treatment abroad that would be useful. In this country, we are used to having shared decision-making with a doctor before starting treatment, and that is very much where we come from. Maybe in countries where it is insurance-based the patient is viewed as more autonomous, and they pick and mix treatments independently. However, we are not coming from that culture and we are not used to that. In a way, therefore, the clinical aspect – whether seeking a particular treatment in another Member State is clinically good for me to do, would be important and could be built into prior authorisation.

Q157 Lord Trefgarne: Having had the clinical input, you then have to get prior authorisation from somebody.

Ms Bentley: Yes. The important thing from our point of view is that what patients everywhere will want is the best clinical outcome, over and above whether they can say, “I’ve had the right to go and look for it”. That is the most important thing. If prior authorisation safeguards the stability of the healthcare delivery and the service in the home state, I think that is important and valid.

Q158 Baroness Morgan of Huyton: You have already covered some of the potential disadvantages as you see them. There are two in particular that we are interested in that you have not raised, which are the issues around pockets of medical specialisation and the potential disincentive for home states to develop procedures that are delivered abroad. Can you explain a little more about that?

Ms Bentley: I want to stress here that we are lay people and in no way experts. Our train of thought on these things is “If that happens, then logically that might happen”. The logic for us is that, if there is any movement of patients for a particular procedure to one particular

country, the resources will follow that; the expertise and the best people will follow that; and that resource at home may well shrink, leaving those who do not take that choice at home with possibly a poorer or weaker service. An example here, for instance, may be paediatric care, where you have, for the very best reasons, a few centres of excellence of paediatric care. There may be concerns that, in the local General District Hospitals, paediatric expertise and levels of care are now not quite sufficient. This, smaller scale example, may be something that could develop on a larger scale.

Q159 Baroness Morgan of Huyton: Internationally, you mean?

Ms Bentley: Yes. Again, that is only if the volumes increase. However, you cannot tell how the volumes will increase, once you provide greater clarity about a patient's right to seek treatment abroad. The other issue is reduced training opportunities. Trainee doctors in any state will only receive the training done at the hospital where they are training. If patients are going somewhere else for that procedure then, by default, they will no longer have the same access either to watching or carrying out the procedure themselves. We have seen that with the Independent Sector Treatment Centres to some extent, which took on basic orthopaedic work and which as a result meant that the trainees in hospitals did not have access either to seeing or doing those procedures initially, because those ISTCs did not run training.

Q160 Chairman: Could I just follow through, to get your thinking from a patient's point of view about the question of prioritisation? If you are telling us that in your experience most patients would like to have care at home, near home – and the Minister told us that most people who went abroad went for maternity care, possibly because they would be nearer their original home – where do you see the priority of this in terms of the healthcare needs of the patient?

Ms Bentley: I am sorry, could you repeat that about maternity?

Q161 Chairman: You were talking earlier about how people need care nearer home. There is a clash, is there not, in terms of limited resources, between how much money is spent on sending people abroad and paying for them abroad and how that affects the present Health Service and continuing to develop services at home? I wondered what your perspective was on that prioritisation, from a patient's point of view.

Ms Bentley: I think that this is very difficult, because the flow could be two-way. In fact, lots of your resources at home may be going to provide care for people coming from other states as well. As far as I can tell, therefore, it is very difficult to carry out workforce planning just in the UK, based on the needs of the population, et cetera. However, once you have it opening up on an EU level and you have to predict what that demand will be – patients from other Member States may then decide “The UK is a good one, but we fancy Germany the next year” – that could be very destabilising and priorities will be much harder to predict.

Q162 Lord Lea of Crondall: Right from the beginning, your memorandum gives eight disadvantages and two advantages. It seems to me, the way you have been addressing it, a bit more like 10-nil. Do you have any contact with patient groups in other parts of the European Union, to see whether you ought to think more about people who come this way? Would I be right to say that most of your remarks have related to people going the other way?

Ms Bentley: Absolutely, and yes, we do not have contacts with patient groups in other EU states.

Q163 Chairman: That is very helpful of you. Do you think that we have covered the points you would wish to have covered?

Ms Bentley: I probably have a few more but I could always submit them in writing.

Chairman: Certainly, please do let us have anything else you would like to tell us. Thank you very much indeed. It was very clear.

Memorandum submitted by the Royal Pharmaceutical Society of Great Britain

Examination of Witness

Witness: **Mr David Pruce**, Director of Policy and Communications, the Royal Pharmaceutical Society of Great Britain, examined.

Q164 Chairman: Mr Pruce, I will just say welcome and that we are extremely grateful for your giving us your time and for the evidence that you sent to us in advance. All of these things are valuable. As you may realise, it is a rather important directive and there is a lot of work to get it right. This Committee is therefore grateful to all the witnesses for that. I will ask you the same question at the beginning, about the current uncertainty in relation to cross-border healthcare. You said in your written evidence that there is still uncertainty, particularly about the application of the ECJ judgments. Could you expand on those comments, referring to examples of problems caused by the current uncertainty and the extent to which you think the Commission proposal addresses these problems?

Mr Pruce: In our written evidence we were reflecting the views of many commentators, and in fact the views put forward by the Commission itself in drawing up this directive. I am not sure that we have specific examples, therefore. I guess that one of the things that we have concerns about, though, is what “undue delay” actually means. It is a term that has not been well defined; there is continuing uncertainty about what it means, and that in particular certainly needs sorting out.

Chairman: We are going to move on to the potential disadvantages with Lady Morgan.

Q165 Baroness Morgan of Huyton: In a sense it is a continuation, because is it disadvantage or is it confusion? Obviously there is already Regulation 1408/71, and to some extent that is what most of us are probably used to on our holidays. There is already some confusion about what that does and does not deliver; so in terms of the new proposal how can

that confusion be sorted and, in a sense, how can we avoid greater confusion? What advice would you have on any new legislation?

Mr Pruce: To a certain degree it adds another level of confusion and uncertainty. Under Regulation 1408/71, if appropriate care cannot be provided without undue delay – which is the difficult phrase – then a patient is authorised to go abroad and any costs will be met from the public purse. However, if a patient elects to go for treatment in another Member State under this proposed directive, they require prior authorisation for hospital care – another term about which we believe there is potential confusion – which requires an overnight stay of at least one night. I believe there is also other healthcare in a separate list, and that tends to be specialised or costly treatment or treatment that presents a particular risk. The proposed directive will allow patients to seek any healthcare in another Member State that they would have been provided at home, and they would be reimbursed up to the amount that would have been paid had they obtained this treatment at home. That is a difficult concept for people to understand and to define. Essentially, we are concerned that patients may bear the financial risk of any additional costs that arise. On the one hand, therefore, you have all costs being paid and potentially, under this directive, you do not have all costs being paid. We would like to see the interaction between the current regulation and this directive made explicit. We would also like a framework for determining what undue delay actually is, so that people have some certainty about the level of reimbursement that would be determined, so that they can make an informed decision. As the previous commentator said, it is pretty impenetrable and, for the average citizen, let alone people who have studied it carefully, it would be deeply confusing. One of the things that we would suggest is that you would need a very simple guide for patients, so that they could make that sort of informed decision and know whether they are likely to have to pay for anything extra or whether everything is likely to be covered.

Q166 Chairman: May I just ask a follow-up on that? I think the distinction between the directive and Regulation 1408/71 is a very important point. Do you think that patients, having been confused about that, may not pursue appropriately the fact that they could get free care under one system and find themselves opting for one where they have to pay? How do you think they will be clear about that?

Mr Pruce: Unless they have the ability to understand the regulations and the interplay between the two – I would certainly be very confused by it – and unless an individual could afford to take the risk that they might end up paying, I would expect people to opt for the certainty. Certainly if I were in that situation I would opt for certainty rather than risk.

Q167 Baroness Perry of Southwark: I was very interested in your submission, where you raise the issue that patient safety requires the exchange of information about whether the professional is fit to practise. I would like you to expand a little on the suggestions you have made as to how this might be tackled, and what you consider the impact would be if those changes were not made in the directive.

Mr Pruce: I think that there are two main issues to consider. When patients cross borders to receive treatment or when health professionals cross borders to provide services, there needs to be good co-operation and exchange of information. That is not only about the patient's medical history but also about the health professional's fitness to practise, an assurance that they are currently competent and that they have language competence. There is no legal requirement for healthcare regulators to have real-time, web-based, searchable lists of registered practitioners. We do. In the old days, we used to publish a register once a year. As soon as it was published it was out of date, because practitioners had either retired, were struck off the register for disciplinary offences, or had died. What we need to be able to do is provide assurance to healthcare practitioners who will be working with people from other states that they are actually still fit to practise. The concern we have is that you could have

someone coming from another Member State who has a proceeding against them currently. They could therefore travel from state to state, if you like, with that disciplinary action never catching up with them. We would like to see this proposal strengthening the ability of healthcare regulators to require their counterparts in other Member States to disclose fitness to practise information. Currently there is Directive 2005/36/EC, which requires collaboration on information exchange. However, what we have found is that some regulators are prevented from exchanging information because of fairly rigid national interpretations of data protection legislation. We would therefore like it to be an absolute requirement to share information and that regulators should disclose and exchange all relevant regulatory information. The other situation we have is that health practitioners may provide care on a temporary and occasional basis under the directive I mentioned before. There, the practitioner does not join the register of the home Member State but is still governed under their Member State's regulations. They may have completely different standards to us, particularly around the continuing assurance of competence. We have introduced mandatory continuing professional development; we are likely to introduce revalidation, to provide an assurance that somebody was not only competent on the day they registered but actually remains so. Currently, we cannot impose that on people coming in on a temporary or occasional basis. They will therefore be working to the standards of their home Member State and not our standards. Again, we would suggest that Directive 2005/36/EC should not be excluded from the principle of exchanging information, and we would like to see the same fitness to practise and continuing competence criteria that we apply to our own practitioners applied to those who come on a temporary and occasional basis. I hope that is not too impenetrable; it is fairly technical.

Chairman: It is very helpful. You mentioned language, and Lord Lea will pursue that question.

Q168 Lord Lea of Crondall: How insuperable an obstacle is the issue of language? This may be a useful way of putting it in a nutshell. In the UK, with someone who only speaks Urdu for example, how do we get round that? It is not that a lot of people can speak Urdu. Presumably you have questions and answers in Urdu to show people and you ask them to tick them or, if they cannot speak, they get a friend. Can you compare this with what the language problem is when you get to another country, and remind the Committee how it would be viewed in another way? We ought to be thinking about French people coming here as well as English people going to France.

Mr Pruce: We already have problems in many communities where the first language of the majority of the community is not English. I was contacted by a pharmacist whose two main communities were Vietnamese and Polish. The pharmacist was seeking patient information leaflets in Vietnamese and Polish – which was challenging, to say the least. We have to explain to patients how to take their medicines. There are pictograms that we can use, which are pictorial symbols, to try to explain. Often, though, it comes down to using relatives. Certainly I have had 12-year-old relatives trying to explain to their mother how to take medicines. It gets more complicated if it is a medicine for a fairly confidential condition, such as emergency hormonal contraception, where it is very difficult. What we are concerned about here is that, if an English patient goes abroad, they will need to make sure that they can communicate with whoever is providing healthcare to them. If they have any sense, they will choose treatment in a country where they either speak the language or they have a fair assurance that the healthcare providers are educated in their language. I have had that situation with a son who had a broken foot and I was very grateful that the Spanish doctor could speak English, because otherwise I would not have been able to explain the problem to him. It is a critical problem. The other issue is that you want to be able to share notes. If a patient is treated in, say, Poland, you want to be able to have the notes brought back to this

country and understood by whoever is providing continuing care – which is often quite difficult. We have enough problems with transferring information between hospital and primary care and vice versa, without language problems and just on exchanging information. The other problem we foresee is in understanding prescriptions, which is a particular issue for pharmacists. The pharmacist must be able quickly to interpret what the doctor means and some difficulties may arise in differences in drug names, variations in the abbreviations used – we write most things in code between ourselves and doctors – dosages and directions. One example we came across was a brand name Acepril for a drug that is marketed in the UK, and its generic name is captopril.

Q169 Lord Lea of Crondall: That is nothing to do with going abroad, is it?

Mr Pruce: No. However, if that prescription were issued for Acepril in Switzerland the doctor would have meant enalapril; if it were issued in Denmark, the doctor would have meant lisinopril. Three completely different drugs with the same brand name in different Member States. We see the potential for great confusion because of that, and that is one particular issue. The Food and Drug Administration in the States identified a whole series of drugs where either the brand name was the same or very similar to brand names in other countries. That is one area where you could get potential confusion.

Q170 Chairman: But there is some movement, is there not, to try to get some European continuity in prescriptions? You might say something about that.

Mr Pruce: There is some movement on a standard prescription.

Q171 Lord Lea of Crondall: And standard handwriting maybe?

Mr Pruce: I could not possibly comment! There are moves to have a standard prescription and a standard format with standard information. That does not necessarily get over the

differences in drug names. There are some differences in generic names and certainly many differences in brand names. One of the areas where we have particular concern relating to language is English language competence for EEA nationals wishing to come over. Currently we are unable to require evidence of English language competence from EEA nationals wishing to register with us. We have to register EEA nationals and cannot demand evidence of English language competence. We can from every other country in the world and we do, including Australia, New Zealand, et cetera. Once on our register, they are bound by our code of ethics that requires pharmacists and pharmacy technicians to have sufficient language competence to undertake their role. They can therefore get onto our register and practise. We then would have to catch them, if you like, determine that they do not have language competence and remove them from the register. They can therefore gain entry to our register and immediately be in breach of our code of ethics. We find it bizarre that we cannot ensure that there is sufficient language competence for a member of another EEA state to come and practise here. That is something we have deep concerns about.

Q172 Chairman: Is there a remedy for that?

Mr Pruce: We would certainly like this issue to be written into this directive, so that we would be able to ensure language competence.

Q173 Lord Trefgarne: Is this a big problem? Are there dozens of pharmacists coming from Eastern Europe, say, who cannot speak English?

Mr Pruce: There are. There are certain countries in Europe that train more pharmacists than they need. When we had an influx of people from Poland – they now seem to be going back – we had Polish pharmacists coming over. There are certain areas of the country where there are shortages of pharmacists and some companies have actively recruited in other countries, be that Spain or Poland; it could be Bulgaria or Romania.

Q174 Lord Trefgarne: I am not bothered about Polish pharmacists; I am bothered about Polish pharmacists who cannot speak English.

Mr Pruce: Absolutely. Similarly, Polish pharmacists and Spanish pharmacists may be very good; it is whether they can speak English to an acceptable degree, so that they can communicate with patients and understand what the patient is saying to them.

Q175 Lord Trefgarne: I want to ask you about prior authorisation. You have referred in your evidence to the lack of clarity of this requirement, and it is clearly an important part of what the Commission proposes. What do you think we can do about what the Commission proposes to meet your concerns?

Mr Pruce: I think that, quite simply, it is what is the scope of prior authorisation? It depends on the definition of “hospital care”. You might have a procedure in one Member State that is considered to require an overnight stay and therefore falls within this; however, in another Member State it might be dealt with as a day case or even in primary care. That is increasingly the pattern that we are seeing in this country, where we are actively trying to move care from hospital out to primary care or to deal with more cases as day cases. Different standards are applied in different countries.

Q176 Lord Trefgarne: You therefore define hospital care as care requiring an overnight stay?

Mr Pruce: That is the definition which seems to be used in the directive; whereas increasingly we would do things as day cases or within primary care. It is something that really needs to be clarified and we would want to look at that. You may also want to look at things like dental treatment, where there might not be a prior authorisation. We all know that there are problems with NHS dental treatment. Is there a concern that that might then move to other countries?

Chairman: We did not completely bottom out the issue of prescriptions. I will ask Lady Young to follow that through in relation to things like the top-up question.

Q177 Baroness Young of Hornsey: You have touched on some of these issues, but perhaps you could say what your view is of the draft directive's provision for EU-wide recognition of prescriptions. What do you consider to be the potential advantages or some of the drawbacks of such a provision? Do you think that it may have some impact on equity, particularly in the context of this notion of people being asked to top up?

Mr Pruce: The UK Government has already passed legislation that permits recognition and dispensing of prescriptions written by EEA and Swiss doctors and dentists. To a certain extent, therefore, things have already moved on in this country. Those prescriptions have to comply with UK prescription requirements and no controlled drugs may be included in that; similarly, drugs that do not currently have a marketing authorisation in this country. You may have a drug that is marketed in, say, Germany but not in this country. We would not be able to dispense on an EEA prescription a drug that is not marketed in this country. We agree that that is right. Otherwise, we have the difficulty of having to import medicines from Germany, which is doable but is expensive and time-consuming. It certainly would be an advantage to have a standard template for all EU prescriptions, and that could be designed to comply with legislation from all Member States. I think that is entirely doable and would be a sensible move. Again, it is language. It is understanding what is written on the prescription; it is understanding the problems of different drug names, as I have already covered. It also comes down to what happens if a pharmacist is unclear. Currently, if a pharmacist is unclear or concerned about, say, the dose of a medicine that has been prescribed, we will contact the prescriber and tactfully say, "Did you really mean to prescribe this?". It becomes very difficult if the prescriber is in Poland and does not speak English. Being able to clarify the prescription in that sort of circumstance is virtually impossible. One of the things that we

have said to our members is “If you are unclear, you do not have to dispense a prescription that has come from the EEA or Switzerland. You have to apply your professional judgment to it, in the same way as you would to any other prescription”. Pharmacists would also need to be confident that it was written by a genuine doctor. As I have mentioned before, one of the problems is in accessing information about who is currently on the Swiss, Polish or Bulgarian medical registers. We have provided our members with a long list of ways of accessing that information, but it is by no means certain that they would be able to get that information.

Q178 Baroness Young of Hornsey: You mention in your written evidence that, in some cases of medical negligence it is down to the prescription having been mishandled in some way or another. That seems to be yet another layer, especially in terms of liability and who is responsible for that. Do you see that as an added issue?

Mr Pruce: It is an added complication, because you potentially have a pharmacist in this country, a doctor in a different country, working to different standards, with different expectations on whether the pharmacist would contact them, the degree of interaction between the two, and so on. It is often quite complicated, assigning liability when an error occurs; for example, a prescribing error that is then not picked up by the pharmacist. One particular case had something like an 80:20 split on responsibility. The pharmacist should have been able to detect that the prescription was incorrect and should not have dispensed it; equally, the doctor should not have prescribed something that was incorrect. It just adds another layer of complexity to an area that is already fairly complex.

Q179 Baroness Young of Hornsey: Could we return to this issue of equity and whether these proposed changes will have some impact upon equity, especially with regard to this patient top-up issue?

Mr Pruce: I think that the whole area of top-ups is something that is being addressed through the Richards review and his report. Our view is that the need for top-ups should be minimised anyway. It is difficult to determine how much this will affect it – the fact that they can get it in another country because it is allowed in that country and not allowed in this country. Decisions would have to be made on whether that is funded. It is unclear as to what those decisions would be.

Q180 Baroness Young of Hornsey: It would be done on a sort of case-by-case basis?

Mr Pruce: Probably.

Q181 Chairman: Are many drugs marketed in other EU countries that are not available in the UK? What is the sort of volume?

Mr Pruce: I could not tell you off the top of my head. However, in many areas of the EU, for example, it is routine to treat low blood pressure; in this country we would not treat low blood pressure. There are a number of drugs that are marketed in this country that would not be marketed across the whole of Europe, simply because there is not a profit in it, or some countries tend to restrict the sorts of medicines that are available. There are certainly differences across the whole of Europe.

Q182 Lord Lea of Crondall: Could I ask a slightly broader question? I think that it is perhaps worth asking, for information and for our report. You obviously do have contact with your parallel bodies in France, Germany, et cetera, and presumably there is some sort of European co-ordinating secretary in Brussels, or something like that. Can you tell me how all of that works and do you think that your views would be very much the views of your French colleague or your German colleague?

Mr Pruce: There are co-ordinating groups within Europe. There is the Pharmaceutical Group of the European Union, which is where the trade bodies associate. There are groups of regulators. To be perfectly honest, I have not looked at what our counterparts in Europe are saying, and I know that they are coming to a view at the moment. Unfortunately, therefore, I could not say ---

Q183 Lord Lea of Crondall: Is there not a council of European bodies, where you have to know what they are saying because you were asked what you think? There is no such committee?

Mr Pruce: There are various groups within Europe where information ---

Q184 Lord Lea of Crondall: It is just not your line within your organisation, but there is somebody within your organisation who does do this liaison?

Mr Pruce: We do liaise with the other bodies.

Q185 Lord Lea of Crondall: It is not your particular job.

Mr Pruce: It is not my particular job, but also the Europe-wide group has not yet come to a view on it. I think that they will be fairly shortly, but they have not yet. They are therefore going through the motions of coming to an agreement.

Q186 Chairman: When they do, no doubt you would be able to let us know what that view is, which is the important point that Lord Lea raises?

Mr Pruce: Absolutely, yes.

Q187 Chairman: Before we let you go, can we just ask you about these contradictions? You raised this apparent area of contradiction between these two statements, which appears in your evidence in section 12 on page 7, where you say that there are difficulties between no

new entitlement for treatment being created and the right to receive a medicinal product authorised for marketing in the Member State of treatment even if this is not authorised for marketing in the home state. You also mention reimbursement in relation to this. Can you tell us a little about how you see this and what should be done to make sure that this is reconciled in the final directive?

Mr Pruce: It is probably easier if I give an example of what might happen. Take a scenario of a German patient who comes over to this country to have an operation. We would treat any post-operative infection with our standard antibiotics. That would be standard practice in any hospital. However, if the antibiotic that is chosen is not marketed in Germany for whatever reason, would it be reimbursed? Our standard practice might be to treat with a third-generation cephalosporin. If the drug chosen was not one that was available in Germany, it is unclear to us whether it would be reimbursed by the German authorities. Would the prescriber then be under pressure to use only medicines approved in the home Member State of the person coming over, say in Germany? And how would the patient have any idea about whether they are being treated with something that is available in their home state – particularly in the case of, say, a post-operative infection where treatment would probably be started before they were fully *compos mentis*?

Q188 Chairman: So that, although the proposal does not change the right of a Member State to define healthcare, you are saying that the practical complications will in fact lead to that not following through in relation to the second area of treatment?

Mr Pruce: If a prescriber were aware that the patient was not going to be reimbursed for their treatment back home, they would be under pressure, be it moral or financial, to prescribe something that the patient could be reimbursed for. That potentially skews treatment away from the standard treatment in this country.

Q189 Lord Wade of Chorlton: Listening to your evidence and the previous evidence, in your view there are a lot of disadvantages with what is proposed here. By and large, do you think that it is worth doing or do you think that the disadvantages will be so difficult to solve that in fact it will create more downside than upside?

Mr Pruce: I think that it is worth getting it right. That is our view. If what this is trying to do is ensure that everyone is guaranteed a minimum standard of healthcare from all Member States and that they are able to move from one state to another to receive it, that seems to us to be laudable. There are practical issues that need to be solved, and that is what we have tried to point out in our evidence. If some of the practical issues can be solved, it would make the situation more workable. We already have a situation where people do cross boundaries and there is uncertainty that needs to be solved. If this is going to solve it, then that seems to be a good idea.

Q190 Chairman: It is a question of where we are.

Mr Pruce: We are where we are, yes.

Chairman: I did not ask you to state your name at the beginning, Mr Pruce, but we will take it as read! Thank you very much indeed for coming and giving us evidence. Again, if there is anything else you want to say to us, do let us know in writing.