CONTENTS

Oral Evidence

PA Consulting Group
Written Evidence 1
Oral Evidence, 23 October 2008 5

Rt Hon Dawn Primarolo MP, Minister of State, Department of Health
Written Evidence 16
Oral Evidence, 30 October 2008 19
Supplementary Written Evidence 30
Further Supplementary Written Evidence 34

Medical Defence Union and Medical Protection Society
Written Evidence, Medical Defence Union 36
Oral Evidence, 6 November 2008 37
Written Evidence, Medical Protection Society 43
Oral Evidence, 6 November 2008 45
Supplementary Written Evidence, Medical Defence Union 52

Patient Liaison Group of the Royal College of Surgeons England (RCSE)
and Royal Pharmaceutical Society of Great Britain
Written Evidence, Patient Liaison Group, RCSE 53
Oral Evidence, 13 November 2008 55
Written Evidence, Royal Pharmaceutical Society of Great Britain 60
Oral Evidence, 13 November 2008 65
Supplementary Written Evidence, Patient Liaison Group, RCSE 70

General Medical Council and the Nursing & Midwifery Council
Written Evidence, General Medical Council 72
Written Evidence, Nursing & Midwifery Council 74
Oral Evidence, 20 November 2008 76
Supplementary Written Evidence, General Medical Council 87

NHS Confederation and Royal College of Nursing
Written Evidence, NHS Confederation 88
Written Evidence, Royal College of Nursing 91
Oral Evidence, 4 December 2008 94
Supplementary Written Evidence, NHS Confederation 104
Supplementary Written Evidence, Royal College of Nursing 112

British Dental Association and British Medical Association
Written Evidence, British Dental Association 114
Written Evidence, British Medical Association 116
Oral Evidence, 11 December 2008 120
Supplementary Written Evidence, British Dental Association 130
Supplementary Written Evidence, British Medical Association 130

UNISON and Unite
Written Evidence, UNISON 132
Written Evidence, Unite 135
Oral Evidence, 18 December 2008 136
Supplementary Written Evidence, UNISON 146
Supplementary Written Evidence, Unite 146
Commissioner Androulla Vassiliou, EU Health Commissioner, European Commission
Oral Evidence, 15 January 2009 147
Supplementary Written Evidence, European Commission 156

Written Evidence
Association of British Insurers 157
Faculty of Pain Medicine of the Royal College of Anaesthetists 160
Richard Fowler 161
General Osteopathic Council 164
Law Society of England and Wales 165
Royal College of General Practitioners 168
Supplementary Written Evidence, Royal College of General Practitioners 172

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Memorandum by PA Consulting Group

OVERVIEW OF THE DIRECTIVE

PA Consulting Group (PA) welcomes the opportunity to respond to the call for evidence issued by Subcommittee G (Social Policy and Consumer Affairs) regarding the EU directive on the application of patients’ rights in cross-border healthcare.

The current demand for cross-border care stands at 1% of the total healthcare budget spent by EU Member States, equating to approx €10 billion. Since 1998, a number of cases brought before the European Court of Justice have asserted the rights of the individual to receive reimbursement for healthcare received in other EU Member states. This EU directive aims to create a clear framework for cross-border healthcare within the EU and clarify the rights of the patients seeking this option of care.

The underlying theme in the directive is patient choice. After many years of uncertainty it outlines the right of patients to choose their healthcare provider irrespective of where they live within the EU. This choice is now underpinned by the patient’s right to reimbursement for the care they receive as well as protection around quality and safety. Choice is a powerful tool which has been shown to drive innovations and productivity in other areas of the economy and is placed at the heart of the modern NHS. It is hoped that these same benefits could support transformation in the healthcare industry throughout EU member states.

Another key benefit of the directive is that it provides leadership around the development of more robust structures to facilitate European cooperation in healthcare. One key example is in the area of “e health”. To this end many Member states have been doing extensive work on their information and communication technology (ICT) structures to support the transfer of patient health information between local and national health providers. When taking “ehealth” forward to a European level it is hoped that EU facilitation would be done sensibly, respecting the stages of “ehealth” development in each Member state. While standards are necessary to bring some Member states up to a level, they must not be so rigid as to hinder other countries such as the UK who have always provided leadership with their ICT development and innovation.

In conclusion this directive gives leadership that has been long needed in the area of cross-border health care while giving Member states room on interpretation and implementation. It also has strong objectives in the area of healthcare quality and improving European cooperation on healthcare, which will not only ensure standards in cross-border healthcare but will add to health quality overall.

REPLY TO QUESTIONS

1. Question 1 (a list of the questions are attached in Appendix A)

1.1 Possibly the strongest advantage to patients having the right to access healthcare in any EU member state is choice. In all areas of business and industry, choice and the competition it introduces causes the subsequent market forces to drive innovation and improve practice. In the case of health this would hopefully have a positive effect on domestic care provision and in the long term drive up standards and deliver improved health outcomes.

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1.2 There are many circumstances where a patient might seek to exercise choice and access cross-border healthcare. In the case of some populations it allows them to access the most convenient care available to them. This is of particular importance to populations along border areas such as in Northern Ireland, where UK citizens accessing the nearest point of care find themselves going across the border to the Republic of Ireland and vice versa. It also assists those who work or retire in another EU Member state.

1.3 In member states where waiting lists are long and patients have difficulty accessing non-acute treatment (eg orthopaedic elective procedures), the right to go abroad and seek treatment in Member states with “spare capacity” means that they now can receive the same high quality care, when suitable and necessary. This is a particularly important benefit for patients waiting for elective treatments, who may be forced to endure non-acute, but significant symptoms, most commonly pain, for a longer, and in some cases, unacceptable period of time. Avoiding the impact on work commitments (eg sick leave, reduced productivity, side effects of medication) are additional issues that should be seen as important benefits to both patients and society.

1.4 While some of the important disadvantages include logistical issues, language differences and the added bureaucracy of reimbursing costs, one other key disadvantage to accessing healthcare abroad might be the upsurge in “health tourism”. As a result of this, it may put consequent burdens on those Member states who have perhaps invested several percent of GDP to tackle waiting lists or improve overall quality of care.

1.5 From a clinical and patient point of view, ensuring continuity of care is a major challenge and could have an adverse impact on treatment outcomes. National structures (electronic medical numbers, adequate national IT health links and capacity of community services and social care etc) are likely to struggle to ensure the continuity of care for patients who have travelled abroad for an elective procedure and expect to be rehabilitated at home or supported if there are complications. Similar concerns arose when the government introduced independent sector treatment centres in this country in 2002.

1.6 Of course over a long period of time the “market forces” factors created by choice might help resolve some of these issues, but in a mixed economy of state and privately run systems, some will fair better than others and the question is whether the benefit to a small minority of patients who exercise choice in this context is worth the potential disruption to the health systems of Member states or indeed the additional cost to tax (or insurance) payers.

2. **Question 2**

2.1 Since 1998 uncertainty in this area has led to patients having to go to the European Court of Justice to assert their rights to receive financial reimbursement for the care they received in another member state. It took a landmark ruling in 2006 for the UK’s National Health Service to reimburse a patient who had spent nearly £4,000 treatment abroad due to a prolonged NHS waiting list in the UK. All this uncertainty meant that these patients had to undergo a great deal of stress to get clarity on EU Citizen’s rights and entitlements and receive timely reimbursement.

2.2 Problems have also arisen around who takes responsibility for clinical oversight in all aspects of “cross-border healthcare”. The uncertainly around this not only affects patients who were subject to clinical oversight outside their own Member state, it also covers harm arising from care received by patients remotely (eg telemedicine, remote diagnosis and prescription laboratory services etc), harm from care delivered by a healthcare provider resident in another state and finally health professionals who move temporarily to another member state and are responsible for harm that arises from care they provide. When something has gone wrong, problems have arisen as there was a lack of clarity around who was responsible and which jurisdiction would deal with it.

2.3 The Issue of clinical liability needs to be analysed very closely to identify how exercising the choice to go abroad for cross-border care effect patients and clinicians. Consideration needs to be given to situations where an NHS doctor was to recommend cross-border treatment, or if the Directive effectively required such choices to be available through national systems such as Choose and Book. Most patients would follow their Doctor’s advice and, if they are then affected by clinical oversight, could the NHS become liable for the quality of any care delivered overseas, as it was “prescribed” or recommended by the UK clinician?

2.4 There are also problems with patients gaining access to follow up care. Entering into the health care channels in their own member state after receiving treatment abroad can be difficult and getting follow up out patient appointments or rehabilitation at the time it is needed can prove challenging. On the other hand, if patients are able to access follow up care, unless their new clinicians have received a full and comprehensive handover on the extent and type of treatment they have received abroad, (along with relevant translation if in another language) it is difficult for the domestic clinician to give the best quality care to the patient.
3. **Question 3**

3.1 The EU needs to:

— Gather data to gain an understanding of the extent of cross-border care. The objective is to have a system that collects and reports on cross-border care in such areas as conditions being treated, patient flows, cost differentials and clinical oversight. This is important for audit and long term planning.

— Clarify the rights of the patient in regard to all areas of cross-border healthcare. The objective of this action is to clarify the rights so that Governments of the member states can legislate, enforce and protect these rights.

— Clearly outline the process/pathway that patients from any member state must go through to access cross-border care. The objective of this action would be to provide a system that would allow citizens to find out about their rights and to understand how to go about accessing the care they need.

— Clarify the funding for treatment. Should there be agreed criteria for determining the level of reimbursement EU citizens are entitled to when seeking treatment abroad? What about the process of reimbursement to ensure that it happens efficiently? Should EU legislation ensure that payment is made in a certain time period?

— Clarify and outline the process by which quality and clinical oversight will be dealt with in all aspects of cross-border care. The objective is to set quality standards and have access to a system at a national level allowing people to report issues regarding quality and poor care.

— There is a need across all member states to continually improve health outcomes and improved wellbeing (QALY indicators). Cross-border care could stimulate improvement for some countries health indicators.

4. **Question 4**

4.1 At a high level the proposed directive meets all the objectives that have been outlined above. Yet the timing and governance of the Directive’s implementation will be very important. For example the implementation of ICT standards to align nations can encourage some jurisdictions to work towards a standard while hinder others who have achieved a similar effect internally with an alternative (or preceding) standard and wish to move forward. Judging this will be difficult.

5. **Question 5**

5.1 The directive allows member states to implement a system of prior authorisation for “assumption of costs for hospital care provided in another member state”. This condition recognises that while the chances of cross-border care undermining a member state’s medical and social services are slim, the ability to plan for service provision within hospitals in a jurisdiction was still very important. This is possibly the only condition that should be imposed on citizens’ rights in the area of cross-border care.

6. **Question 6**

6.1 Within the directive the cost limits on treatment are set at the costs that the Member state would incur for the provision of treatment within its own jurisdiction. This in itself is a fair cost for the Member state. Yet it does not support equality nor does it allow all areas of the community to access cross-border healthcare. The ability to access health care abroad will continue to encourage wealthy patients to go abroad for their care as they can afford the additional costs (flights, accommodation for companions/next of kin, etc) that are incurred. These costs, unless covered by the individuals member state as well would bring the choice of care abroad out of the reaches of those on lower incomes.

6.2 There are also cost issue surrounding high-cost Member states vs. low-cost Member states. Citizens in states where healthcare is inexpensive would effectively be prevented from travelling, or they would travel for “top up” care and be willing to pay the difference. There are also further issues around cost for the UK and the NHS—do they fully understand the true costs of treatment. Current NHS billing arrangements may not accurately reflect costs, and distortions could land NHS with delivering care to non-NHS patients at a loss.
7. Question 7

7.1 One major practical impact of the proposal would certainly be the impact on day-to-day health provision of language. For patients who do not have English as their first language, face-to-face interpreters or access via a telephone service such as Language Line would have to be made available at all times while the patient was staying as an inpatient and also if they attended as an outpatient. Effective communication is a prerequisite to ensuring patient safety. For purposes of collating clinical information, consent for procedures in addition to explanation and instructions for treatment it would seem fair that if a UK Centre had agreed to provide treatment to a patient, they would be responsible for these additional costs and would be entitled to incorporate these costs into any charge for care services.

7.2 The other major problem would be the provision of follow up and the management of post-treatment complications and the burden of responsibility. As mentioned already the follow up care after certain operations/treatments can impact greatly on the success. This can include medical, nursing and allied health professionals, who have clinical specialisation in an area. Some treatment is delivered in the days or weeks post input, but in some cases it can continue for months afterwards. If a patient returns to their own country and are then unable to receive the same level of expertise, the overall outcome can be affected adversely. Therefore it would seem that if a patient decides to remain in a Member state for the duration of their care (in and outpatient care) they would be allowed access the required follow up and be appropriately reimbursed for the cost of treatment by their own member state. It would be up for discussion if their Member state would be liable for the other additional costs (accommodation, living costs etc).

8. Question 8

8.1 This directive limits the medical conditions covered for cross-border care to those that would be provided in the patients Member state or those where waiting lists may be unacceptable. This seems a fair limit on conditions covered. Yet how practical is the imposition of eligibility of condition and clinical standards in a cross-border care situation, particularly where condition guidelines may leave considerable room for clinical judgement. To what extent would it be reasonable for clinicians overseas to comply with UK guidelines and vice versa? A hypothetical example could be a patient moving overseas to get a second chance to receive a treatment denied in the UK as eligibility guidelines could be different? If the EU wishes to address this they could be drawing up an EU list of conditions and treatment. This leads to the core issue over who owns the list of eligible treatments—insurer or EC—and the governance issues around changing that list.

9. Question 9 and 10

9.1 It is important that the opportunity to benefit from cross-border healthcare is made equally available to citizens and not just confined to the wealthy or able. Yet putting this into practice may be more difficult when there are inequalities in healthcare in the UK itself. The report “Healthcare for London” outlined that two London electoral wards Westminster and North Greenwich, which, geographically are only a few miles apart have a seven year difference in their life expectancy. As currently only 1% of the total EU healthcare budget is spent on cross-border healthcare and Commission surveys have shown that most patients prefer to have their healthcare needs addressed in their own country, it could be argued that redressing inequalities in the UK NHS might be of a higher priority than ensuring that cross-border health care is available to all.

10. Question 11

10.1 Cooperation and communication between Member states together with robust systems (Case management systems, integrated e-healthcare records etc) to support such activities will facilitate better health care provision, smooth transitional care, improve continuity and follow up arrangements as well as improving the overall patient experience. In addition treatments centres in Member states with “spare capacity” would be able to provide such treatments, enabling the sharing of the overall health burden across the EU member states. Mutual Recognition of prescriptions would be beneficial but other issues need to be considered, such as drug availability and supply in host countries and drugs not included within a National Formulary.

CONCLUSION

In conclusion this directive gives leadership that has been long needed in the area of cross-border healthcare. It sets out a framework and gives clarification on the choices available to EU citizens as well as their right to reimbursement.
It also has strong objectives in the areas of cross-border quality and safety and around improving European cooperation. These will not only ensure standards in cross-border healthcare but will hopefully add to health quality overall.

26 September 2008

APPENDIX A

LIST OF QUESTIONS AS OUTLINED BY THE HOUSE OF LORDS SELECT COMMITTEE

Question 1: What do you see as the general advantages and disadvantages of patients having the right to obtain health care in Member states other than that where they reside? In what circumstances might patients seek to exercise any such right?

Question 2: What problems do you think have arisen as a result of the present uncertainty in respect of EU citizens’ rights to obtain such cross-border healthcare and to have the costs of this reimbursed by the Member State where they reside?

Question 3: What need do you see for EU level action in this field and, if you do see such a need, what objectives should such action have?

Question 4: What is your view of the extent to which the Commission’s proposed directive will meet the objectives, if any, that you judge action at Community level should have?

Question 5: What conditions, if any, do you feel that Member States should be allowed to impose on citizens’ rights to seek healthcare in another EU country—and to what extent do you think the draft directive satisfactorily makes provision for these conditions?

Question 6: What limits, if any, do you think there should be to the level of costs which Member States should be obliged to reimburse to citizens who obtain cross-border healthcare—and to what extent do you think the draft directive satisfactorily makes provision for these conditions?

Question 7: What is your view of the likely practical impact of the proposals and of how they would affect day-to-day healthcare provision in the UK? For example, could language difficulties present an obstacle?—Who should be responsible for after care (out-patient and in-patient)?

Question 8: What is your view of the need to limit the medical conditions for which treatment could be sought in this manner?

Question 9: How important do you feel it is to ensure that opportunities to benefit from rights to cross-border healthcare are, in practice, made equally available to all citizens and are not confined to just the wealthy or well-educated who may have the knowledge and ability to take advantage of their rights?

Question 10: How do you think the aim of such equality of access should be achieved and to what extent do you feel that the draft directive is satisfactory in this respect? To what extent, for example are the provisions on the availability of information sufficiently robust?

Question 11: What are your views on the provisions set out in the draft directive for cooperation between Member States, including: the mutual recognition of prescriptions; the establishment of European reference networks of healthcare providers; e-health; and the management of new health technologies?

Examination of Witnesses

Witnesses: Mr Andy Mullins, Partner and Head of Health, Mr George MacGinnis, Managing Consultant, Dr Stephen Black, Principal Consultant, and Dr Chris Austin, Principal Consultant, PA Consulting, examined.

Q1 Chairman: We are very grateful to you for taking the time to come. You will probably have gathered that you are the first of our witnesses, so you are going to be, if you like, setting our thinking going in relation to all of this. We think it is an extraordinarily important inquiry because I doubt whether some of the issues have been really fully explored anywhere as yet, so we see it as our responsibility to make sure we do look at the issues in some depth. If we do not get through everything today, we are very happy for you to send supplementary evidence or further answers to any questions that have not been reached. As you know, today we really do want to look at the conceptual issues around this Directive and we are looking for help in that, so perhaps you would begin by saying briefly who you are.

Mr Mullins: My Lord Chairman, can I start by saying thank you very much for inviting us along to give evidence and to contribute to the important work of the Committee. We are delighted to be invited and the reason why we contributed to this in the first place was that we see this as a particularly important issue
for health organisations throughout Europe. Perhaps it might help, as you say, for me to say a little bit about who we are and to introduce my colleagues. PA Consulting is a British management and technology consultancy firm with global reach. We have some 2,000 employees around the world based down the road just in Victoria. Those 2,000 employees all own a little bit of the business, so we are a bit like John Lewis in that sense, so we are employee-owned. We have a long track record and a history of delivering change successfully across the public and private sectors and our work in health is perhaps one of the most significant areas that we are involved in, so each year we will be involved in something like 100 different assignments in the UK, Ireland northern Europe and, more recently, the Middle East. Our work ranges from supporting governments in looking at the design of complete health systems, on the one hand, to working with individual hospitals, clinicians and managers to help improve the care that they deliver to patients. It is with that background and that interest that we come today to offer our views. We do not have all the answers to some of the things that, I know, you will be considering, but we certainly have some views and we hope that that will contribute to your thinking and debate. With me today giving evidence are Dr Stephen Black, Dr Chris Austin and George MacGinnis. My name is Andy Mullins, a Partner with PA and I lead on PA’s work in health in the UK.

Q2 Chairman: Do you want to make a short opening statement?

Mr Mullins: If I may, I would be delighted to, yes. After many years of uncertainty, we think this Directive clarifies the rights of patients to choose their healthcare provider, irrespective of where they live in the EU. It is proposing to underpin this choice with the patient’s right to reimbursement for the care that they receive as well as some protection around quality and safety. In that sense, the Directive provides leadership that has been long-needed in the area of cross-border health while also giving Member States some room for interpretation and implementation. There are some areas that we would welcome, but there are also some areas that we are more cautious about and, if I may, I would just like to outline those for you now. Specifically we welcome five areas. The first area is the clarification of entitlement to treatment in accordance with the legislation and standards that apply in each Member State, so, for us, that seems to be a key point. The second is the requirement for minimum standards around the monitoring of healthcare providers’ complaint systems and so on. The third is the clarification that patients only seek reimbursement for treatment to which they would be entitled in their home system and that prior authorisation systems may be introduced by the Member States for hospital care. In our view, that is essential for stability for individual hospitals or indeed for some Member States’ systems as a whole. The clarification that Member States are not obliged to treat a patient from another Member State if it were to be to the detriment of other patients with similar needs, we also think, is an important point which this Directive makes. Finally, in terms of the areas which we welcome, the fifth one, we also welcome many of the cross-border co-operation ideas on healthcare, including recognition of prescriptions, clinical reference and technology assessments as well, but we will go on to talk a little bit about our worries around some of the comments on e-health in a second. One of the things that we did recently, in preparation for some of our thoughts around this Directive, was to survey 2,000 people through the polling organisation, YouGov, to get some of the general public’s views around this particular Directive. You may be interested to hear, and I am sure this reinforces what you will already know, that the majority of UK respondents are strongly in favour of the right to access cross-border healthcare in the EU, some 58 per cent. Interestingly, and particularly when you hear the accents of my colleagues, there is stronger support in Northern Ireland and Scotland. We think that the difference may be explained by the longer waiting times for elective care in those areas. Interestingly, although the majority of respondents were in favour, 24 per cent said that they would not seek treatment in another EU country under any circumstances, which I think was a bit of a surprise to us; we did not think it would be quite as high as that. The other thing that we noted as well is that the over-55 age group were also stronger supporters than other age groups. When we looked at the reasons why people would travel overseas or indeed just across borders, respondents felt that the length of wait was the key factor, and I mentioned earlier about increases indeed in Scotland and Northern Ireland. The second most popular reason was the reputation and the experience of the EU healthcare provider, so people would be attracted to go to an alternative provider if their quality or their reputation shone out. I will just briefly go through the areas where, I think, the devil is in the detail, if that is okay, and then I will pause.

Q3 Chairman: Well, shall we go into our questions and, if you think we have not asked about the issues that you want to raise, then we can come back or you can let us have that. You are going fast and we need to absorb the issues fairly steadily because we are going to be thinking in a matrix way, across all the issues with a number of witnesses, but that was very helpful. You have had notice of the questions in
advance, and the thing which has spurred this on is of course what you have just mentioned, which is the legal uncertainty which has come from cases like the Watts case in Europe and the issues about equality and cost, and we are going to be asking you a bit about that, but it is clear that the evidence you talked about those issues that need clarification. Would you expand on those comments? You have mentioned some of them in your list, but you may, from the rest of your comments, want to talk about how we are going to get that current uncertainty resolved and what we need to look at. Then, to what extent does the Commission proposal, because this is what we are really interested in, respond to those problems and what do you think the implications would be if we did not agree to such legislation?

Mr Mullins: We think there are two key areas that are a challenge. One is around the right to reimbursement, so, on the one hand, we welcome what the Directive is suggesting around clarifying reimbursement, but we are concerned that it does not go far enough, it is not clear whether reimbursement will mean the patient paying up-front and then reimbursed subsequently or whether the provider or the payer organisation of the Member State will pay directly to the hospital of treatment. Our view is that in either the Directive, or implementation guidance, our Government ought to seek to clarify this or there will be some groups of patients who will not be able to afford or take up, or exercise, that choice. The second area, which I think we mentioned in our original report, was around clinical oversight and the responsibilities for managing the patient pathway between Member State and the providing hospital. If we think about what happens right now when a patient moves between one provider and another, there is a dialogue between clinicians and the GP within the UK around the pathway that that patient needs to go through. So before that patient may be transferred, there is clarity around what follow-up care they may receive when they go back home and they are under the care of their GP. What is not clear in this Directive is the mechanics of how that will happen across the European Union. Our view would be that provider organisations ought not to accept patients unless there is a clear pathway, and they would have a moral duty, we believe, to ensure that that pathway was in place before undertaking any treatment. Providers will need to be clear about what they are responsible for and what they are not responsible for. Even if the provider were saying, “We will operate on your hip and will be providing, as part of our package, a period of physiotherapy in the three days after”, they should be seeking assurance that the necessary arrangements are in place when that patient returns home to continue with further recovery care. In the UK, that could be the responsibility of the GP and in other Member States that may well be the responsibility either of the insurer or indeed of the patients themselves, but, in terms of provision, we need to be clear about who is responsible for that. We think, this is an area that requires quite a bit more guidance.

Chairman: And leads to quite a complex administrative process.

Q4 Baroness Neuberger: I ought to declare an interest to start with as a Director of Voluntary Health Insurance in Ireland, plus previously Chief Executive of the King’s Fund, but I am really interested in your written evidence where you are pretty clear that there is a real benefit to be had for patients in increased choice, and you then say quite a lot about what might flow from all of that. If we go right down this line, with all the caveats, as you have just said, where do you think we end up because you have already said, and it was extremely interesting about the YouGov evidence, that there is a very positive view about cross-border healthcare and that older people are particularly interested, and I think we know that because there are some procedures where we are already seeing some signs of that, so where does this go and how do we make sure it goes there properly?

Dr Black: When we thought about what the benefits of choice are, and this applies inside England at least and is improved by having access to other countries, the obvious benefit is that some patients will be able to get care that is in some way better than what they were able to access locally, so it might be more timely, it might be more convenient or it might actually be of a different quality. It is up to the patient to decide what they mean by some of those things and choice has the benefit that, as things change over time, the patients will respond by making different choices, so we do not have a government committee deciding, “This is what’s good for you” and taking a long time to do it, but patients can change their minds and next week they will want something different from this week. However, that is not the biggest benefit of having choice in the system. We believe the biggest benefit is in the way it changes the incentives for hospitals. There has been some analysis inside the NHS and in many other places where, if we get the incentives right, then hospitals become much more responsive to the things that patients want. If patients can move away from their local hospital because the waiting lists are long or because they do not like the sorts of wards that hospital has or they do not perceive the hospital to be of a high quality, then that gives that local hospital a strong incentive to fix those things or, at least in systems where the money follows the patient, the hospital will lose some of its income,
and that is a very, very powerful incentive to drive up improvements in health. We think that is actually the largest benefit for the system of having patient choice. What is likely to actually materialise may actually not be hugely significant in terms of the volumes of movement because you do not need that many people to make a different decision to provide quite a strong incentive for a hospital, and our view, looking forward, would be that we probably would not see large movements at the whole-hospital level. What is likely to happen would be to particular departments or particular specialties where there are either short-term or long-term problems. For example, in the UK, there are some orthopaedic departments which have very long waiting lists. It is much better than it used to be, but they are still long and patients do not like that. Those patients in that specialty may be the sorts of patients who would choose to move to another country, so it may be that that effect would be relatively localised. In the long term, these things may actually balance out, so the incentive for that department to improve may well lead to having very short waiting lists in the future, in which case the patients will no longer be moving abroad, so the effects are not permanent, but will be things which may be self-correcting through the mechanisms and the incentives that choice actually creates. There are some big benefits in terms of capacity across the whole of Europe. If we have particular problems, particular shortages in some countries, then the ability of patients to choose to move may actually help use European-wide capacity much more effectively than insisting that all patients are treated in their local hospital or in their home country, so that is a range of different benefits that we perceive coming.

Q5 Baroness Neuberger: I might just pick you up because you talk a lot about the patient and the patient being able to choose, but in many cases it may well be the payer as opposed to the patient. It may be in response to patient comments on the quality of service received, but it could be, and it would not apply so much to the NHS, but it would apply to other European countries, that a purchaser would say, “Actually, the sort of orthopaedics we’re getting here are rubbish. We’re going to send all our orthopaedic cases of elective surgery to Spain”, and that will be presumably because the patients have put the pressure on the system. Is that part of the benefit that you see, that it is not only the patients, it is how the payers respond to patient pressure?
Dr Black: I think the answer to that depends a little bit on the structure of the health economy in different countries.
something in at a national or EU level that takes GPs’
decision-making powers away. They are the ones
who are going to have to agree prior approval for
travel overseas and we have to be careful that we do
not agree something that takes that power away from
them. That is the only way that we are going to be
able to manage or gatekeep this flow of patients. How
other countries are going to do it, I do not know.

Q10 Lord Trefgarne: This leads to the headline
where a particular hospital says, “Sorry, we can’t
take any more foreigners because we’re full up with
our own people”.

Dr Black: I think there is an additional issue of
practicality to bear in mind that situation and it is
partially to do with, if the patient at least is choosing
or even in fact if the payer locally is choosing to send
patients, why would they continue to try to send
patients to an unwilling hospital which did not want
to take them. As we have said, one of the reasons why
people choose to go is because they get faster
treatment. If too many people choose to go, the
treatment can no longer be fast, so it actually sets
limits and the mechanisms of choice may provide a
very strong practical limit to how far these
movements can actually occur, whereas, on the other
hand, if we have spare capacity in a hospital for doing
angioplasties, why not use that for Spanish patients?
Why would we have spare capacity? It may be a good
thing for the NHS as much as for the Spanish.

Chairman: I think we will come back to some of this,
and certainly this leads into the next area very clearly
because we are wanting to look at equity and all of
this does take us into the equity question.

Q11 Baroness Perry of Southwark: Yes, indeed. Just
to make a bridge in, as they would say on Radio
Four, there are tertiary referrals, and this has been
quite a risk for many years, has it not? I was a
Governor for some years of Addenbrooke’s NHS
Trust and of course that includes Papworth, and we
had a lot of tertiary referrals from hospitals at
Papworth and going back 10/15 years I think that
had been happening. Is this not something which
might happen where you get areas of extreme
specialism, so to speak, and very high-profile
specialism where there are tertiary referrals from
hospitals, and this would be hospital consultants, not
patients making a choice?

Dr Austin: I am speaking from a background of being
a clinician myself, having only recently come into the
consulting industry. Previously I worked at a
foundation trust here in London in a sub-speciality
area of medicine—diagnostic and interventional
radiology. Certainly some of the things that we
experienced, even within our own department
because of the sub-specialisation that is taking place
have led to these kinds of phenomena and behaviours
among patients within the UK itself. It is actually
even extending outwith those borders internationally
because of the reputations of the different procedures
that we are actually doing. Obviously, there is a
balance that you have to strike here and I think the
Directive does put some caveats into it, although I
agree with the comment that what is meant as a
“detriment” to the actual services that are being
provided locally needs to be clarified. What is also
essential though is to recognise that these centres of
excellence need to have the capacity to develop
themselves and grow. In my experience within a
couple of years at my particular hospital, I started to
see the kind of ebb and flow of very skilled clinicians
not just within the UK, but from abroad who were
being attracted to the practice and bringing patient
groups with them. I think that the Directive should
not necessarily curtail that kind of ebb and flow; that
is what happens in academic institutions, in
universities across the globe and we do not want to
put barriers on universities, saying, “This shouldn’t
happen”. If a facility which has that expertise and
that sub-specialisation can brand itself well, it should
have the potential to build that capacity, and that
capacity, as long as it is generating income and good
outcomes clinically, will attract and generate more
individuals who can come and do the work.

Q12 Baroness Perry of Southwark: That does raise
the equity issue of the patients who might wish to buy
their way into one of the areas of high expertise. I
know that you have highlighted in your written
evidence the issues of equity that arise. Could you
explain the concerns that you have and what
solutions you think might be offered?

Mr MacGinnis: Most of our concerns were actually
about the mechanism of the way it would work in
supporting people who were in other ways
disadvantaged from being able to pay for that, but I
suppose I would just like to come back to the sense of
how we got to this question today. I think there are
some underlying principles that are quite important
in understanding this queuing and rationing system,
firstly, the bit about clinical need, and it must be an
absolute thing, that this is not some bureaucratic
right to join a queue, to get a place and then find the
queue all filled up, but clinical governance over who
has priority, and then that critical issue we pointed
out earlier, that the provision of care to people across
borders should not be to the detriment of the home
population, and that is a clinical judgment, in my
view, and must always be central. The side-effect actually is probably that waiting lists become the mechanism by which the flood of angioplasties is prevented from happening in one place or another, but I do take your point and I think that is actually not easy to govern and may be subject to other influences and interests at the local level, but that clinical judgment, I think, needs to be at the core of it. In the other areas, what we were concerned about more was whether this Directive would actually provide another means of having a two-tier NHS, those who had a cash reserve and could travel and those who could not.

Q13 Baroness Perry of Southwark: Travel or top up.
Mr MacGinnis: Well, a degree of top-up probably is unavoidable if there is a core operation for which the NHS would have a tariff and would have paid for anyway, so going and having extensive rehabilitation that was above and beyond anything that you could get on the NHS might well be an option for people who choose to top up and travel overseas, as it would be if they paid private medical insurance, so I think there are some of those mechanisms there. Possibly of more concern is actually whether the way that the payment mechanism is implemented actually serves as a further barrier to people who do not have a cash reserve, so we thought it was very important. The proposal enshrines pre-authorisation and we would go a stage further and would want to see that pre-authorisation with a payment mechanism which, for the NHS-funded elements of it, did not touch the patient. We actually think there may be some side-benefits in terms of some of the other issues that you have addressed questions on if the NHS retains the payment control because that then gives you an ability to do a little bit more in judging quality and ensuring that you get documentation or whatever back, so we think that is there. Then there are a few even further issues, if you delve into that, around travel, accommodation, subsistence, particularly for people for whom the NHS pays, and I think this actually then does become a rather difficult issue and I am not going to suggest that there are any answers from our point of view, but I do think that it raises important equity questions. If someone would be entitled to free transport and support to exercise choice anywhere within the UK, then there are similar issues with this. Probably the overriding principle should be that that package should be contained within the UK tariff, so, if the medicine is cheaper and the accommodation adds to that cost, but is within the reimbursable limit, I think it would be fair if that was covered, but there is probably a multitude of sins in there and that actually creates quite a difficult mechanism for the NHS to actually get their mind round and govern.

Dr Black: I was going to add a very short comment because there are some myths around who benefits from having a choice. I think the original work on this was done by Professor Julian Le Grand, and he argues that the middle classes are very good at getting choice, even in systems which do not notionally allow it, so they get it, but actually choice for all patients, especially if it does not involve them having to pay any of their own money, is actually very empowering for the people who currently do not get much choice, lower socio-demographic groups, and in fact they marginally want it more than the middle classes, according to public surveys.

Q14 Baroness Perry of Southwark: Can you name a survey that showed that?
Dr Black: Not directly, but I think the work will be work done by Professor Julian Le Grand, who was the Government’s Health Adviser under Tony Blair. Mr Mullins: We could perhaps provide that as supplementary evidence.

Baroness Perry of Southwark: Because some of the evidence, I know, in education is that, where people are offered choice, the lower socio-economic groups tend to be the ones who least want to exercise it, but it is the sharp-elbowed middle classes who do.

Baroness Neuberger: On the point of the lower socio-economic groups, was there not also evidence that suggested, and you actually cited the YouGov survey, that older people are stronger supporters of cross-border healthcare than other age groups? Is it not the key to some of this that older people feel disempowered in some health systems across the EU and therefore, look for choice elsewhere? Again, would you have some of the data on that because that could be very useful, which would tie together with the information about socio-economic groups?

Q15 Chairman: Just to add to that, in a previous inquiry which we have just undertaken on organ donation, it was quite clear that people from minority ethnic groups found it far more difficult to access healthcare of all sorts and, therefore, there were issues around organ donation. It would be really interesting to know what would happen to those groups in this market.

Mr Mullins: We would be very happy to submit the data that we have collected through the YouGov survey and that may help to answer the question. I cannot promise that it absolutely will, but we will certainly provide the data that we have.

Q16 Baroness Perry of Southwark: On the issue of equity, you have raised in your written evidence the question of whether the NHS should give more priority to using its resources to help reduce the existing health inequalities within the UK than to
ensure that cross-border healthcare is available to all. In the light of your extremely expansive experience with the UK health sector, do you have any feeling for the majority of opinion amongst health professionals and patients on that subject?

Mr Mullins: Sometimes you write things in reports and you think, “Actually, that’s quite inflammatory”, and we perhaps did that deliberately! We may have presented a slightly false choice there because I do not think any health professionals, managers or clinicians actually sit down on a day-to-day basis and say, “Am I going to tackle inequalities or am I going to send this person overseas?” Having said that, I think the sentiment that we were trying to get across is that there is a very real danger that, if we do not get the implementation guidance right for this Directive, it could distract managers and clinicians disproportionately towards the few people who want to exercise their choice in this area and away from the important work that they do day to day, and I think that is really the sentiment we meant, so I do not think there is a danger really that the money that is involved in this, given Dr Black’s comments about the numbers involved here, I do not think that is the issue here.

Q17 Chairman: The issue really is about the undermining of the clinical judgment that we were talking about earlier.

Mr Mullins: Yes.

Q18 Lord Trefgarne: I would like to raise two related topics. The first is a question of prior authorisation, on which you have already touched in your remarks, and, allied with that, the question of eligible conditions, where, it seems to me, the eligibility can be determined at the prior authorisation process on occasions, if not always. You have expressed support for prior authorisation as a concept at least, but what are the drawbacks to such an arrangement and what are the implications of excluding non-hospital care from the prior authorisation which is, I think, what the Commission have in mind?

Dr Black: I think there are two big issues with prior authorisation. The downside of it and the downside of having lists of approved conditions is that it could be quite bureaucratic, it could involve a lot of paperwork and a lot of delay in the process of getting people care. That may not be such an issue, depending on how you actually set up a prior authorisation system, but I think it is very important to understand why prior authorisation is necessary and it comes in if you compare different healthcare systems around the world. The ones which seem to get things right, which end up with reasonable amounts of control over both clinical quality and their budgets, are the ones that have incentives lined up so that somebody has to worry about whether we are doing too much or whether we are paying for too much, so the systems that work least well, like large parts of the North American system, have no primary care gatekeepers and, if anything, they dramatically overtreat the population and that leads to runaway budgets for healthcare and patients getting so much treatment that it actually harms them, and there is very solid evidence that that is true in North America. If you read some material produced by, for example, the Dartmouth Atlas project, we could refer you to that. Now, prior authorisation is necessary because it is the primary lead, certainly for the NHS, to put the incentives in the right place to stop runaway spending and indeed to actually act in the clinical interests of patients who will sometimes say, “I want this treatment”, even when a clinical judgment would say, “This is going to harm you rather than benefit you”. For both those reasons, we think that what the NHS does, which is it effectively has GPs acting as gatekeepers to hospital care, that system is essential and we do not want to undermine that by what we do in allowing people to go abroad and go to different European countries.

Q19 Lord Trefgarne: That ties up with eligibility, does it not, so that, while prior authorisation is being considered and no doubt mostly granted, at the same time the eligibility can be determined? The important thing is to ensure that the clinician faced with the patient is not told to wait days or even longer while, first of all, the authority and then the eligibility is determined. That is the drawback, is it not?

Dr Black: Yes, and the advantage of having some list of approved conditions would be that the only person who has to do anything is the GP and, once they have made a referral, then everything else is fine. A very large amount of work happens in a fairly small amount of types of surgery or types of procedure, so, if countries can more or less agree this list, it takes out a great deal of paperwork and delay in the process.

Q20 Lord Trefgarne: And, if you have a condition on the list, prior authorisation is not required?

Dr Black: Well, I am not certain I would phrase it like that because you still have the clinical judgment as to an individual patient.

Q21 Lord Trefgarne: But, if the doctor is happy, then you are in business?

Dr Black: Yes.

Q22 Lord Trefgarne: But he cannot determine the eligibility?

Dr Black: It is very hard to write bureaucratic rules which determine clinical thresholds for treatment, you need some clinician involved in the loop, but the
benefit of an approved list is no more bureaucracy beyond that point, no more paperwork. But it is not the patient deciding they need a hip replacement and then getting one automatically because it is on the list.

Q23 Lord Trefgarne: Eligibility has other considerations too. A patient might present themselves in France, saying, “I am eligible in England”, but they happen to be foreign nationals and they are not eligible in England, and that might take a long time to sort out.

Mr Mullins: That is a very good point and I think it probably would.

Lord Trefgarne: It is not just medical eligibility, it is national eligibility.

Chairman: Having to prove eligibility will be quite a significant matter.

Q24 Baroness Young of Hornsey: All of this is extremely complex of course and, when we start to look at liability, we move into even more complicated areas, if that is possible. Now, you have indicated that the issue of clinical liability needs to be analysed very closely. Do you think that the draft Directive is helpful, useful or productive in that area and do you think it helps to give more certainty to patients and clinicians?

Mr Mullins: I think our comments in this respect clearly will not be from a legal perspective, but more from the managing, change and implementation aspects. I do not know, Chris, whether you had a view on that one.

Dr Austin: Again, as Andy is saying, we are not approaching this question with our legal hats on. In order to answer the question there is a need for detailed analysis particularly around the legal framework and focused on some of the indemnity issues and the requirements for insurance to protect clinicians who are offering treatments in the various Member States and that there is some kind of coherence across the board that recognises these packages. The way we have approached this question is to look at it from a management point of view and a business point of view and at the risks involved. From this context the process is really important, the process around ensuring that a patient can make the complaint, and that the process is transparent. Patients should know how to go through this journey—it can be a very complex journey for the patient and for the clinicians from that point of view. The process also has to be timely. The Directive does not necessarily need to say all of these things, but it needs to make clear that the process set out by a Member State meets these basic criteria so that, when this becomes an issue for individuals, they can have some kind of guidance of what to expect. I think the other thing to keep in mind with all of this is that, as the patient is going through the journey, there is an agreed consensus on how outcomes are going to be reached and how the compensation schemes are going to be reached. Finally, the overriding principle here is one of ownership, who takes ownership for developing these processes and making sure that they are in place, and that there is some kind of agreement by the Member State that is going to be able to deal with the issue. Again, for us, it is not so much about the Directive saying, “This is exactly what you need to do”, but, because this is a process-driven thing, it is about making sure that the Directive says, “You have to make sure you do the right implementation and ensure that your processes are robust enough that patients can go through the system without legal wrangling between Member States disputing who is responsible and who is going to pay up”.

Q25 Baroness Young of Hornsey: I think this is probably another area which we will need to go into more deeply because it is not only about complaints about medical treatment of course, it is about a whole range of other issues as well that one might want to complain about. I will move on to my second question, which is not totally separate from this, but it is about the issue of language. Going through my mind is how do you make a complaint when you are dealing with several different languages, and of course across the Union there are 23 official languages and here in London we have many different languages. How are we going to cope with this? Who takes responsibility for providing services, like interpretation and so on and so forth?

Dr Austin: Language is an important thing and it is essential that the Directive actually acknowledges how important it is in this kind of scenario. We know, as clinicians working in London, how important it is. It is important for lots of reasons. It is important for the patient, for the patient’s family and relatives and for the clinicians and the staff who are looking after them. So, whilst we think it is important to recognise it, we take a different stance in terms of what we think the Directive should say about language. We do not think the Directive needs to prescribe who provides it, nor who needs to fund it, and let me kind of explain my thinking around this. We are approaching this issue from the point of view that providers, who elect to provide a service to a patient and agree in advance to taking that patient, need to provide whatever package of care is going to be essential for them to do the job appropriately. Now, if I put my clinical hat on, for instance, and put myself in a hospital in Paris and I choose to accept a referral from a patient coming from the UK, I need to ensure that there are certain things in place, otherwise I am putting myself in a liable position. If I do not have the services to
communicate with my patient, to communicate with the referring clinician appropriately and in my language to understand the problem, I am not going to accept the duty of care and say, “Okay, come on over”. We think that it is the provider Member States that really need to be thinking about this service.

Q26 Chairman: What about the commissioners? What are their responsibilities, the commissioners of the service, the people who are referring? It is all very well for the person who is going to provide the service, but what about the GP or the health authority? Earlier, we were talking about the pathway through the service. I wondered what you thought the responsibilities for the Commissioner would be for setting out the pathway and making sure that all these things are in place, including the language?

Mr Mullins: I think you raise a very good point and one of the angles we thought about when we were putting these answers together is that, if we think about the system of choice that Steve described earlier, patients are less likely to choose providers if they are not going to provide the full range or package of services that are going to be helpful to them, and this is a challenge around information which is a separate issue, but providers are going to have to say, “Yes, not only will we operate on your hip, but this is how we are going to look after you. This is the quality of care and the hotel services that we can provide for you, how we might support your family and friends, if they are with you, and indeed, if you do not speak our language, how we will support you doing that”. Now, if those things are not clear and advertised, then I would suspect, when we talk about the PCT’s role and the GP’s role, the GP is less likely to advise and support a patient to take that choice. Firstly, if they do not know that it is there or they are unsure, and I am sure the GP would not do it, but most patients still, I think, would heed what the GP says.

Q27 Chairman: How sure are you that GPs are going to have the expertise to actually make this analysis, bearing in mind some of the recent investigations into GP practice?

Mr Mullins: I am not sure, nor am I sure that they will necessarily always have the time to do that. It is difficult enough for supporting the offer of choice in this country alone, let alone between countries.

Q28 Baroness Young of Hornsey: It is partly a matter of process, is it not, but it is also, as you say, about information because we talk very blithely, I think, about choice, but then there is choice and there is real choice, is there not, and, if you are not in possession of all the facts and information and able to interpret and understand the implications of that, then what kind of choice is it? I think this is a really important area that we need to think about quite clearly and, as you say, the commissioning as well.

Mr Mullins: I entirely agree with you. One of the things that our short analysis showed is that people would make a choice on a small number of factors, whether it is waiting times or indeed location or the quality of follow-up care. It is some of the hygiene factors, if I can put it that way, around it which may actually outweigh their preference for some of those choices. In the absence of real information patients may make a choice they later regret and that is a thing we have to be wary of.

Baroness Young of Hornsey: I suppose there is an element of risk assessment for the patient in that.

Q29 Lord Kirkwood of Kirkhope: Within the Committee’s rules, I am bound to advise you that I become a member of the GMC on 1 January 2009. I want to ask you about aftercare because it is a very important question, and this might be best done by a note because we are a little bit constrained on time, but, from your experience, can you sketch in the numbers that we are talking about here? Is there any data about what is happening at the moment? What is your estimate of what the demand might be? I think there are small percentages, but they could be big numbers, and it would be enormously helpful for the work of the Committee, as we start this process, if we could just get a handle from your background and not just about the statistics, the numbers of people and the flows that are extant at the moment, but could you estimate where this might lead? If everything that could go right did go right, in five or ten years’ time would you be anticipating big flows across these boundaries? It may be that the best way of doing this is maybe to do a note, but could you just say a word about that for the benefit of the Committee before I ask questions about aftercare?

Dr Black: I would not like to commit to any numbers without going out and looking at some analysis that we can conceivably do with current NHS statistics, but I think a general comment would be that I would not think that the overall flows over time would be very large in a sustainable way because, as I said, they are probably quite narrow patient groups, quite narrow subsets of patients, and those people will choose for a bit and then maybe, when things change at home, they will choose to come back to England. We may be able to answer some questions by looking at how patients have chosen to move from hospital to hospital in England where there should be emerging
statistics which tell us a little bit about that exercise, but I think we should probably look at the statistics and reply with a note.

Q30 Lord Kirkwood of Kirkhope: Yes, that would be very helpful and that is the best way of doing that, thank you. You talked earlier, Mr Mullins, about the patient pathway and I am sure that that is absolutely right. Just give me six sentences on what you think a definition of ‘aftercare’ and ‘follow-up care’ would be.

Mr Mullins: Rather than try my layman’s approach, I am actually going to turn to the doctor on the team and ask him to do that one, if I may.

Dr Austin: To answer the first part of the question, we did not use the concept of ‘aftercare’ in our submission, but I think that came back to us in the questions. We are not making a differentiation between the two, but we are using the term ‘follow-up care’ in our document and we include that to be everything post-treatment, from the time of hospital discharge to the point when the best possible clinical outcome has been achieved.

Q31 Lord Kirkwood of Kirkhope: So that includes things that go wrong unexpectedly?

Mr Mullins: I think this is another area to highlight where we think will need some clarification. As you will know, one of the challenges of the introduction of the independent sector in this country has proved to be is: who does the rework if we get it wrong? Of course that has caused all sorts of implications and bad feelings sometimes when that has happened. If we are going to get the guidance right for this Directive, we are going to have to clarify those bits of the pathway as well, so not just if it works properly, but what happens when it goes wrong and what is the redress for that.

Q32 Lord Kirkwood of Kirkhope: Okay, but the key question really is this: supposing you were persuaded that you could not, within the context of the Directive, lock down the requirements for that patient pathway about which you spoke so eloquently earlier, do you think that the merits of doing all of this would be worth the trouble if you could not get that grounded properly in the legislation? If you did not have the confidence that that would be a seamless, joined-up process, is this something that we should think about in terms of not even bothering if you cannot do it?

Mr Mullins: If we cannot ground it, whether it is in the legislation or subsequent guidance or indeed within our own Member State, then I think we would certainly be worried because, and you will know better than I will, a proportion of those procedures will go wrong for whatever reason and, if we have not grounded what happens in those circumstances, then I think that is a worry.

Q33 Chairman: Unfortunately, we are running out of time and clearly the Committee could have continued to ask you a range of other questions, but there is just one more that I would like to ask and that is about co-operation between Member States, which you mention. Of course, we all believe in co-operation as a principle, but it is the practicality that is the difficulty, and we wondered if you would like to expand on some of the issues that you have identified in terms of practicality. I think some of us are particularly interested in e-health and the use of computers, bearing in mind the difficulties some of us have faced with computers in other situations.

Mr Mullins: I have to say you are not alone on that! With that in mind—and perhaps we can do a separate note—we had some thoughts around some of those points on co-operation. But particularly as it is e-health I will ask George to say a few words around that area because it is an area that he is expert in.

Mr MacGinnis: It follows on really well from the continuity of care argument because the exchange of health information in support of people moving is clearly something to be really welcomed. Breaking away from some of the paper cycles and some of the limitations on paper is equally important. What I have flagged is this is the area which is probably, in my view, the most far-reaching and radical element of the Directive and does raise for me some questions about how feasible it is and exactly what the nature of the powers being transferred are. Without really going into much detail, it is probably enough to say that inter-operability in health is an illusive and moving target. For instance, we have had all our GPs computerised for well over a decade now. Only last year was the first time that some GPs could move electronic records when their patients moved to a new GP, and that goes down to the heart of these technical issues. Clinical safety is at the heart of the reason why that has not happened earlier. In solving this this is not a national or a regional problem; it is a global problem. If you look at the national programme, many of the products coming over have been developed elsewhere particularly in English-language countries and the size of the market suggests that. I think the home nations have had quite a good track record of engaging globally in getting the standards they needed to get their programmes delivered. Why is this an issue? Standards generally, while they make sense, normally come with a burden. There is a cost/benefit equation and by being very close to the people who are trying to implement them and commercialise some of this stuff that cost/benefit equation is being solved. I do
not see the same mechanisms in Europe. I do not see the ability to back up a mandate of a standard with a payment mechanism that actually gets everyone's computers upgraded, or however it would manifest itself. Because we are earlier adopters in the UK, we probably stand to lose more than other nations might gain from disturbance to our various national programmes up and down the country, so I think it is a really worthwhile goal. It is an illusive target and I am really not sure that the European mechanism would have sufficient strength behind it and be consistent with subsidiarity to actually follow that through.

Chairman: Is there anybody else on the Committee wanting to ask any other questions? That being so, can I say that if you do have other things that you would like to send us, we would really welcome them. As you can hear, we are already immersed in some quite complex issues around this and you have helped us immensely. Thank you very much indeed.
THURSDAY 30 OCTOBER 2008

Memorandum by the Department of Health (DH)

1. The Government welcomes the House of Lords’ Inquiry into the draft directive on the application of patients’ rights in cross-border healthcare and the opportunity to provide more detail to the Scrutiny Committee. Following the Call for Evidence, we have set out our responses to the questions asked.

What do you see as the general advantages and disadvantages of patients having the right to obtain healthcare in Member States other than that where they reside? In what circumstances might patients seek to exercise any such right?

2. There are routes through existing European Union (EU) Regulations where patients can seek treatment in other Member States. Patients have the right to obtain healthcare that becomes medically necessary during a temporary visit to another Member State, through the European Health Insurance Card Scheme (EHIC). These Regulations, which co-ordinate social security benefits, also entitle posted workers and pensioners (and their dependents) living in another Member State to healthcare, paid for by the home Member State. Finally, the Regulations allow people to apply to their local commissioner to go to another Member State for planned treatment under the E112 scheme. Therefore, there are already circumstances where patients can seek treatment in another European country.

3. In addition to these routes, European Court of Justice caselaw has created a general entitlement, based on the freedom to obtain services, for people to access healthcare (subject to certain conditions) throughout the European Union. It is this caselaw that the proposed Directive aims to codify.

4. The Government notes that patients can now access more information about their healthcare than ever before and the ability to go to another Member State potentially offers other options for patients. The Government will be undertaking more work to assess the potential advantages and disadvantages of patients having the right to obtain treatment in another Member State. Although the European Commission has suggested that the overall impact of the proposals are broadly cost neutral, we will be looking at, for example, the potential impact on the NHS should significant numbers of NHS patients chose to travel overseas for healthcare.

What problems do you think have arisen as a result of the present uncertainty in respect of EU citizens’ rights to obtain such cross-border healthcare and to have the costs of this reimbursed by the Member State where they reside?

5. The Government considers that successive judgments from the European Court of Justice has created some uncertainty in terms of how the case law should be applied in practice. For example,

— what level of reimbursement should a patient receive?
— who determines entitlements from state systems?
— can states protect traditional gatekeeping systems?
— what are the rules for refusing prior authorisation?
— what are the principles of clear and transparent pricing/costing systems?
— We believe it is necessary for patients and governments to have a clear understanding of the rules that apply to cross border healthcare.
What need do you see for EU level action in this field and, if you do see such a need, what objectives should such action have?

6. The Government considers it is helpful to codify the case law and clarify its applications by means of the proposed EU directive. The key objectives of this EU level action should be to:

- Provide clarity to patients about their rights and responsibilities if they wish to seek healthcare in another Member State.
- Respect Member States responsibilities for deciding how to run their own health systems.
- Ensure that the directive recognises that it is for Member States to determine entitlements to state-funded healthcare for their own citizens.
- Provide clarity about the administrative procedures that Member State health systems can implement in order to support a sustainable framework for cross-border healthcare which allows Member States flexibility to manage their health systems.

What is your view of the extent to which the Commission’s proposed directive will meet the objectives, if any, that you judge action at Community level should have?

7. The Government welcomes the draft directive as an opportunity to clarify the implications arising out of the case law. The Government considers that the proposed directive is an acceptable basis for negotiations about the rules which should apply in relation to cross-border healthcare.

What conditions, if any, do you feel that Member States should be allowed to impose on citizens' rights to seek healthcare in another EU country—and to what extent do you think the draft directive satisfactorily makes provision for these conditions?

8. The Government welcomes statements in the draft directive that expressly say that it is for Member States to determine entitlements to state-funded healthcare and that this directive does not introduce new rights to treatment. In addition, it supports the principle that Governments should be able to require citizens to continue to use “gatekeeper” systems (in the UK, this means that a patient is required to consult a GP or other appropriate healthcare professional before being referred to specialist treatment). We also think the directive should be clear that it is for clinicians in the home Member State to determine entitlements and not clinicians from other states.

9. The Government’s view is that the existing case law recognises that establishing a system of prior authorisation is justified should patients wish to seek hospital care in another Member State. We consider that this principle should be clear in the directive. The Government also notes that although the Court has said it has not seen sufficient evidence to justify a prior authorisation scheme being needed for non-hospital care, it has not expressly ruled out such a scheme.

What limits, if any, do you think there should be to the level of costs which Member States should be obliged to reimburse to citizens who obtain cross-border healthcare—and to what extent do you think the draft directive satisfactorily makes provision for these conditions?

10. The Government believes that healthcare costs for reimbursement should be limited to the amount which the home state would have paid for the treatment, had the patient been treated by the NHS, or the actual amount that the treatment abroad cost (if the latter is lower). The Government considers that article 6 currently supports this aim.

What is your view of the likely practical impact of the proposals and of how they would affect day-to-day healthcare provision in the UK? For example, could language difficulties present an obstacle?—Who should be responsible for after care (out-patient and in-patient)?

11. There are likely to be a number of practical impacts, including different clinical pathways in other Member States, different pricing and billing systems, and how to ensure that patients have sufficient information to make an informed choice. This should include information from the NHS about what healthcare a person is entitled to and what level of reimbursement applies. Patients will also need information from overseas healthcare providers about treatments available. Patients will need to be aware that NHS standards will not apply to care received overseas, and that they should make adequate arrangements for insurance and for addressing any language difficulties.
12. Where care is provided in another Member State then that country’s healthcare providers should be responsible for the after care. The Government notes that should the patient need follow up care on return to the UK then they will be able to seek this on the NHS. We will be looking to explore the implications for clinicians of this, including any difficulties in understanding case notes, and also any cost implications for the NHS.

What is your view of the need to limit the medical conditions for which treatment could be sought in this manner?

13. The Government’s understanding is that the directive applies to treatment for all conditions. The Government believes that a person should not be able to get reimbursement for treatment if they have no clinical need for that treatment, or if it is one to which the person would not have been eligible to receive on the NHS.

How important do you feel it is to ensure that opportunities to benefit from rights to cross-border healthcare are, in practice, made equally available to all citizens and are not confined to just the wealthy or well-educated who may have the knowledge and ability to take advantage of their rights?

14. The Government believes that everyone should have the right to access good quality healthcare. First and foremost, we remain committed to providing that on the NHS. In England, patients are already entitled to choose from any provider of NHS services for elective care.

15. Under the directive, patients will be required to pay the costs of overseas treatment upfront and then seek reimbursement up to the level that the NHS would have paid to treat the patient at home. Although some people may be eligible to apply for help with travel costs, the Government recognises that many people may not be able to afford to seek treatment abroad. We will be looking to explore the potential impact on equity during consultation.

16. It should be noted that if a patient is facing “undue delay” then he can already apply to his local commissioner to have the full costs of treatment in another Member State met and that application cannot be refused. However, where “undue delay” does not apply, the Government does not believe it would be an appropriate use of NHS resources to fund treatment costs in another Member State upfront.

How do you think the aim of such equality of access should be achieved and to what extent do you feel that the draft directive is satisfactory in this respect? To what extent, for example, are the provisions on the availability of information sufficiently robust?

17. As indicated above, the Government is committed to providing high quality care and allowing patients choice of any provider in England. There is a route for ensuring that those who need treatment abroad for medical reasons are able to get this, irrespective of ability to pay. This is covered outside the directive and we do not believe the directive therefore needs to specifically address this mechanism.

18. We note that the draft directive specifies that information should be provided in a broad range of means, including electronically. We believe that this will help ensure that information is available to support NHS patients make an informed choice about their treatment and be aware of their rights and responsibilities. For example, patients will need to ensure they have adequate insurance arrangements to cover their treatment. Nevertheless, we have concerns about how much practical information about treatment options in other states the NHS will be able to provide.

What are your views on the provisions set out in the draft directive for cooperation between Member States, including: the mutual recognition of prescriptions; the establishment of European reference networks of healthcare providers; e-health; and the management of new health technologies?

19. In general we believe that there is a role for EU wide co-ordination in some areas of healthcare, particularly where this can share expertise and add value to existing domestic policy aims. However, each provision relating to specific policy areas must be justified on a case-by-case basis; the Government does not consider that it would be appropriate for the directive to be used to encourage cooperative work which does not have the express purpose of facilitating crossborder healthcare.

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1 In arriving at a decision about what “undue delay” means, the European Court of Justice has stressed that this must be based on a clinical assessment of what is a medically acceptable period for the individual clinical circumstances of the patient, and that this assessment needs to be kept under review while the patient is waiting for treatment.
20. The Government recently amended Medicines legislation to facilitate the mutual recognition of prescriptions. The draft directive proposes that the Commission may develop an EU-wide prescription template. We will need to consider if this goes beyond the information required on UK prescriptions. We will also need to consider any measures proposed to facilitate the mutual recognition of prescriptions, such as e-prescriptions, to ensure patient safety is maintained.

21. The Government has been participating in the European Reference Networks pilot project. This presents an opportunity for clinicians to share expertise on the treatment of rare diseases. We support the aim of the reference networks but think their remit should be limited to covering treatment for rare diseases.

22. Concerning e-health, the Government already collaborates on e-health initiatives as part of the European eHealth Action Plan. The Government notes that the provisions in the directive relating to e-health are potentially quite wide. It will be seeking to clarify the scope of this provision.

23. Finally, the Government broadly supports health technology assessment networks as a means of sharing information and good practice but is keen to advocate using existing mechanisms. The Government will want to be clear on funding commitments and organisational structure of any networks.

7 September 2008

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 one—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 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.

Ms Primarolo: Yes.

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

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 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, elicit 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

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1 This remark that non-hospital care is not excluded (from prior authorisation) is in the context of the present European Court of Justice (ECJ) case law.
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.

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2 This remark deals with equity and the fact that we currently reimburse travel for patients in the UK with limited means. We are consulting on the issue of equity in our consultation.
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, their health systems determine that. The only determination. We can see no reason, in determining the criteria for Germany or France; their health systems determine that. The only

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 and 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 cooperation 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 is 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.

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.

Supplementary memorandum by the Department of Health

Thank you to the Committee for an interesting session on the 30 of October. As part of the session, I undertook to write to you and the Committee with further detail on four points:

Firstly, on the issue of the Department’s understanding of what the Commission have in mind regarding a “standard format” for the provision of information to patients.

This “standard format” is referred to in Article 10 of the draft Directive, which states,

“(1) The Member States of affiliation shall ensure that there are mechanisms in place to provide patients on request with information on receiving healthcare in another Member State, and the terms and conditions that would apply, inter alia, whenever harm is caused as a result of healthcare received in another Member State.

(3) The Commission may, in accordance with the procedure referred to in Article 19(2), develop a standard Community format for the prior information referred to in paragraph 1.”

The Government’s response to the suggestion of a Community format for the provision of information is that we feel that this might only work for the very basic and common details shared by Member States. Health provision and services differ from country to country and to try and capture all these on the one form could prove very difficult and be unusable for patients.

Secondly, on the issue of the Department’s view on national contact points, as raised by Lord Kirkwood, in our consultation document we have asked for views on where national contact points could be located and how they could make best use of existing resources.
However, our initial thoughts around the establishment of dedicated “national contact points” is that they should be focused on providing general information only as well as providing links to the National Contact points in other Member States. We do not believe it would be appropriate for National Contact points to be under any expectation that they could provide specific information about service providers in other Member States.

Already, there is information on the EHIC, E112 and Article 49 for patients who may consider or require health treatment in another Member State on Department of Health, NHS Choices and NHS Direct websites.

However, we expect that it would be the role of the local commissioner to provide more detailed information for the patient during assessment, ensuring that they fully understand the difference between E112 and Article 49 when reaching an informed decision. I do not think the national contact point could replace this.

The issue was also raised of how the NHS would deal with issues around the recognition of, and reimbursement by the NHS for, prescriptions issued in another Member State and brought back to the UK by a UK patient to be dispensed for drugs not licensed for use in the UK and/or not recommended by NICE.

Firstly, regarding drugs that are not licensed for use in the UK. Dispensers in the UK cannot dispense a prescription for a drug that is not licensed for use in the UK. We think that Article 14 in the draft Directive ensures dispensers in Member States do not have to recognise prescriptions for medicines that are not licensed in their territory. Since the patient will be unable to get the prescription for an unlicensed product dispense in the UK, the issue of whether they are reimbursed by the NHS does not arise.

Similarly if a patient presents a prescription for an item that is listed in Schedule 1 of the NHS (General Medical Services Contracts) (Prescription of Drugs etc) Regulations 2004 as a substance not to be prescribed in primary care at NHS expense, it is unlikely that the PCT will think it appropriate to reimburse for the prescription.

Secondly, covering prescriptions from another Member State for a drug that would not normally be funded by their local Primary Care Trust (PCT) for example a drug that receives a negative NICE appraisal. Decisions on whether patients are entitled to such drugs at NHS expense would be for their local PCT to make. If a UK patient seeks an NHS reimbursement for a prescription item that would not normally be funded by their PCT, then their case is open to the normal PCT procedures for exceptional circumstances.

If the PCT decides not to fund the drug, (and assuming the drug is licensed and it is a valid prescription), the patient is entitled to have the medication dispensed as a private prescription under the *Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008*. 

In terms of the relationship with “top up” payments, if the EEA prescription is paid for by the NHS, then clearly losing entitlement is not an issue. If the EEA prescription is not paid for by the NHS, in his report, Improving Access to Medicines for NHS Patients, Professor Mike Richards recommended that patients should not lose their entitlement to NHS care if they choose to buy additional care privately, as long as the private element of care is delivered separately from NHS care. The Government published alongside the report, on 4 November, draft guidance for the NHS for consultation that makes this principle clear.

The final set of information I undertook to provide is the detailed information on the current data I have available on who is accessing cross-border healthcare under the E112 scheme. I attach this as an annex to this letter.

I hope that these answers are useful to you. I am sure we will meet again in the coming months on this matter and thank you again for an opportunity to discuss these issues with you.

I await the Committee’s Report with interest, and will be writing to update you following the meeting of the Council of the European Union on the 15/16 December.

12 November 2008

**Countries of Treatment and if Maternity/Non-maternity for E112 Forms Issued in 2007**

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### Crossborder Healthcare: Evidence

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</tr>
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<td>Slovakia</td>
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</tr>
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<td>Spain</td>
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</tr>
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<td>Sweden</td>
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</tr>
<tr>
<td>Switzerland</td>
<td>3</td>
<td>15</td>
<td>18</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>404</strong></td>
<td><strong>148</strong></td>
<td><strong>552</strong></td>
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</tbody>
</table>

Annex 1

**Countries of Treatment for E112 Forms Issued between Jan–Sept 2008**

<table>
<thead>
<tr>
<th>Country</th>
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</tr>
</thead>
<tbody>
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<td>Belgium</td>
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<td>France</td>
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<td>Germany</td>
<td>42</td>
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<td>Greece</td>
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</tr>
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<td>Hungary</td>
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<tr>
<td>Ireland</td>
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<td>Italy</td>
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<td>Malta</td>
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<tr>
<td>Poland</td>
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<td>Spain</td>
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<td>Sweden</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>596</strong></td>
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[Though we do not have a full break down, 561 of these were maternity cases.]
COUNTRIES OF TREATMENT AND IF MATERNITY/NON-MATERNITY FOR E112 FORMS ISSUED IN 2007

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<thead>
<tr>
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<tr>
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<td>Hungary</td>
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<tr>
<td>Italy</td>
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</tr>
<tr>
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<td>Portugal</td>
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<tr>
<td>Romania</td>
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<td>1</td>
</tr>
<tr>
<td>Slovakia</td>
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<td>0</td>
<td>10</td>
</tr>
<tr>
<td>Spain</td>
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</tr>
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<td>Sweden</td>
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</tr>
<tr>
<td>Switzerland</td>
<td>3</td>
<td>15</td>
<td>18</td>
</tr>
<tr>
<td>Total</td>
<td>404</td>
<td>148</td>
<td>552</td>
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COUNTRIES OF TREATMENT AND SPECIFIC TREATMENT GIVEN FOR E112 FORMS ISSUED IN APRIL–JUN 2008

<table>
<thead>
<tr>
<th>Country</th>
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<th>Reason</th>
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<td>Ictal SPECT</td>
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<td>Czech Republic</td>
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<td>Ictal SPECT</td>
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<td></td>
<td></td>
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<td>Hysterectomy</td>
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<td>Finland</td>
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<td>France</td>
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<td>Chemotherapy</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Proton Treatment</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>PVI Ablation</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Brachytherapy</td>
<td></td>
</tr>
<tr>
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<td>1</td>
<td>Chemotherapy</td>
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<td></td>
<td>3</td>
</tr>
<tr>
<td>Hungary</td>
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<td>1</td>
<td>Illizarov Treatment</td>
<td>4</td>
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<td>Italy</td>
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<td>1</td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>Netherlands</td>
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<td></td>
<td>Removal of endometric lesion</td>
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<tr>
<td>Poland</td>
<td>131</td>
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<td>132</td>
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<td>Slovak</td>
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<td>Lymphoedema</td>
<td>8</td>
</tr>
<tr>
<td>Spain</td>
<td>6</td>
<td>2</td>
<td>Orthotics, Casting and Fitting of callipers</td>
<td>6</td>
</tr>
<tr>
<td>Sweden</td>
<td>5</td>
<td></td>
<td></td>
<td>7</td>
</tr>
</tbody>
</table>
Further supplementary memorandum by Department of Health

Many thanks for your letter dated 16 December. I am glad that you found the information provided helpful and look forward to reading your final report.

With regard to your query on who in the NHS is commissioning E112 referrals, please see the attached table below. This lists which PCTs (or local commissioner in Wales or Scotland) recommended authorisation of an E112 form for a patient to travel to another Member State. However, it is important to note that the NHS does not commission E112 referrals. Each E112 request from a patient is examined on a case-by-case basis.

This data covers non-maternity cases in 2007 and 2008. However, it is not possible to provide information around how many requests each local commissioner handled. The GP or midwife who recommends the authorisation of a maternity E112, is not currently captured.

On the issue of the responses to our consultation, we are still analysing and preparing our response to the consultation in advance of publishing the Government response to the consultation. However, we believe that many of the points made to us in consultation responses will have been made to you via written and oral evidence.

We will of course ensure that you have copies of our response to the consultation as soon as is possible.

22 January 2009

Annex 1

LOCAL COMMISSIONERS THAT RECOMMENDED THAT E112 FORMS BE ISSUED FOR NON-MATERNITY CARE IN 2007 AND 2008

<table>
<thead>
<tr>
<th>Bath and North East Somerset</th>
<th>Lambeth</th>
</tr>
</thead>
<tbody>
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<td>Berkshire East</td>
<td>Leeds</td>
</tr>
<tr>
<td>Bradford and Airedale</td>
<td>Lewisham</td>
</tr>
<tr>
<td>Bury</td>
<td>Liverpool</td>
</tr>
<tr>
<td>Calderdale</td>
<td>Lothian NHS Board</td>
</tr>
<tr>
<td>Cambridgeshire</td>
<td>Luton</td>
</tr>
<tr>
<td>Camden</td>
<td>Medway</td>
</tr>
<tr>
<td>Central Lancashire</td>
<td>Mid Essex</td>
</tr>
<tr>
<td>Cornwall and Isles of Scilly</td>
<td>NHS Greater Glasgow and Clyde</td>
</tr>
<tr>
<td>Croydon</td>
<td>NHS South of Tyne and Wear</td>
</tr>
<tr>
<td>Cumbria</td>
<td>Norfolk</td>
</tr>
<tr>
<td>Derbyshire County</td>
<td>North Yorkshire &amp; York</td>
</tr>
<tr>
<td>Devon</td>
<td>Northamptonshire</td>
</tr>
<tr>
<td>East and North Hertfordshire</td>
<td>Oldham</td>
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<tr>
<td>East Lancashire</td>
<td>Somerset</td>
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<tr>
<td>Eastern and Coastal Kent</td>
<td>South Gloucestershire</td>
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<td>Enfield</td>
<td>South of Tyne and Wear</td>
</tr>
<tr>
<td>Fife NHS</td>
<td>South West Essex</td>
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<td>Gloucestershire</td>
<td>Southwark</td>
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<td>Stockport</td>
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<td>Haringey</td>
<td>Surrey</td>
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<tr>
<td>Havering</td>
<td>Swindon</td>
</tr>
<tr>
<td>Health Commission Wales</td>
<td>Tameside &amp; Glossop</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>Hounslow</td>
<td>Wakefield District</td>
</tr>
<tr>
<td>Hull</td>
<td>Waltham Forest</td>
</tr>
<tr>
<td>Kensington and Chelsea</td>
<td>Warwickshire</td>
</tr>
<tr>
<td>Knowsley</td>
<td>Worcestershire</td>
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THURSDAY 6 NOVEMBER 2008

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

Memorandum by the Medical Defence Union

INTRODUCTION

1. The Medical Defence Union (MDU) is the UK’s leading provider of medico-legal services. Our members are over half the UK’s doctors in hospital and general practice, and over a third of the UK’s dentists. Established in 1885, we concentrate on doctor and dentist members practising in the UK and Ireland, though until the 1990s we used to provide benefits of membership in a great number of countries worldwide. Since 2000 we have provided UK medical members who are not indemnified by the NHS with indemnity insurance for professional negligence claims arising out of their treatment of patients in the primary care and independent sectors.

2. Our interest in the draft EU directive on cross-border healthcare arises out of its provisions in respect of indemnity for clinical negligence claims and we would like to comment on certain provisions dealing with this. Article 5 1(d) requires provider states to ensure that “patients have a means of making complaints and are guaranteed remedies and compensation when they suffer harm arising from the healthcare they receive”.

3. We understand this to mean that each provider state will need to ensure indemnity arrangements are in place to cover healthcare provided in that territory, to ensure patients from other member states will be compensated if they are negligently harmed by such treatment. Article 5 1(e) would allow indemnity to be provided by state schemes and insurance, which are the only means of indemnity in most member states; but we are concerned it could also be interpreted as allowing discretionary indemnity to be used for clinical negligence claims.

4. In the UK, discretionary indemnity is not considered adequate and appropriate for healthcare professionals such as physiotherapists, optometrists, chiropractors and osteopaths, and it is anomalous it is used to indemnify some doctors and dentists. We believe this is as detrimental to the interests of UK patients as it would be to patients from other member states who were harmed by treatment provided in the UK.

5. If discretionary indemnity was considered acceptable for cross-border healthcare, this could give rise to difficulties: for example, a German patient who was treated in the UK and negligently harmed by a doctor who was reliant only on discretionary indemnity might not be compensated if the indemnifier decided not assist the doctor with the claim. Of course, a German patient who had been treated and harmed at home by an insured doctor would have received insured compensation.

6. It is in the interests of patients and healthcare professionals in all member states, therefore, that the draft directive is amended so it is clear that provider states are required to ensure compensation for claims in respect of treatment provided in their territory will be available only through state indemnity and/or indemnity insurance underwritten by regulated insurance companies.
INSURANCE v DISCRETIONARY INDEMNITY

7. Most UK doctors who are not NHS-indemnified arrange their indemnity with one of the three medical defence organisations (MDOs), though a few deal direct with specialist insurers. As an MDO, the MDU is alone in providing members, as part of their benefits of membership, with an insurance policy (currently co-underwritten by SCOR Insurance (UK) Limited and International Insurance Company of Hannover Limited), in respect of claims for clinical negligence. The other MDOs provide only discretionary indemnity to individual members in respect of such claims.

8. With discretionary indemnity, the decision to indemnify or not can only be made when practitioners present the indemnifier with the facts of the case for which they are seeking help. MDOs cannot guarantee they will assist members with clinical negligence claims, as to do so would be to carry on unregulated insurance business, a criminal offence.

9. It is a requirement in most developed countries that practising doctors and dentists have adequate professional indemnity insurance in order to protect patients. For example, in the early 2000s in Australia a discretionary indemnifier went into provisional liquidation and the Government responded by passing legislation so that discretionary indemnity is now unlawful in Australia.

10. In the UK, insurance is regulated and provides a contractual right to assistance, subject only to the terms of the policy. Discretionary indemnity is unregulated and provides only the right to request assistance. We believe this is an important distinction as far as the interests of patients and the public are concerned, because regulation provides a high degree of consumer protection that is not available with unregulated financial services.

11. UK discretionary organisations have been known to refuse indemnity when asked by members for assistance with clinical negligence claims. An insurance policyholder who is refused assistance is entitled to an explanation for that refusal and can seek redress through the Financial Ombudsman Service and the courts/arbitration, where a judge/arbitrator will decide if the matter is a breach of contract. A discretionary organisation is not obliged to give any reasons for the refusal and, as there is no contract of indemnity, doctors reliant on discretionary indemnity cannot seek redress for breach of contract and have limited legal options for redress. Insurance is also supported by the Financial Services Compensation Scheme which exists to pay claims in the event that an insurer or other provider of financial services fails. Discretionary providers do not come within this scheme and their members and their patients do not have this protection.

12. A further protection for patients where practitioners are insured is the Third Party (Rights Against Insurers) Act 1930 that provides a patient with rights against a doctor’s insurer in the event that the doctor is bankrupt or dies with an insolvent estate. No such rights exist with discretionary indemnity.

CONCLUSION

13. When damages are awarded in negligence cases, it is imperative that patients know they will receive the compensation due to them. UK citizens are not allowed to “insure” their cars on a discretionary basis, and doctors and patients should not be allowed to rely on discretionary indemnity for clinical negligence claims.

14. In providing for cross-border healthcare, we believe member states will wish to ensure that patients can expect essentially uniform protection wherever in the EU they receive healthcare. The UK (and Ireland) are the only member states where discretionary indemnity is still available and we believe this is neither adequate nor appropriate.

26 September 2008

Examination of Witnesses

Witnesses: Dr Christine Tomkins, Deputy Chief Executive and Dr Hugh Stewart, Head of Case Decisions, Medical Defence Union, examined.

Q99 Chairman: Good morning and welcome. We are really grateful to you for coming this morning. We do see this as a very important inquiry into the Directive and your part of it is something we need to be clear on because I think there is currently a lack of clarity in this area. We had a short debate in the House on health where it became clear that there is lack of clarity at government level at the moment. We are going to conduct the session in two halves, as you realise. We thought it would be better to ask you both the questions; your colleagues then have the benefit of hearing your answers so may be able to elaborate, but we want to leave you time at the end for any other remarks you may want to make. You can give us
supplementary evidence if you think we have not amplified the questions that you would have liked us to ask. I am going to ask the Medical Defence Union to start. Could you begin by giving your name and your position for the record and then we will proceed with any statement you wish to make.

Dr Tomkins: My Lord Chairman, thank you for inviting the Medical Defence Union here today. I am Dr Christine Tomkins; I am the Deputy Chief Executive of the Medical Defence Union.

Dr Stewart: I am Hugh Stewart, Head of Case Decisions at the Medical Defence Union.

Dr Tomkins: If I may make an opening statement, the Medical Defence Union is the UK’s leading provider of medico-legal services. Our members are over half of the UK’s doctors in hospital and general practice and over a third of the UK’s dentists. We were established in 1885 and we concentrate on doctor and dentist members in the UK and Ireland although until the 1990s we used to provide the benefits of membership in a great number of countries worldwide. Since 2000 we have provided members as part of their benefits of membership with indemnity insurance for professional negligence claims arising out of their treatment of patients in the primary care and independent sectors. It is important to remember that patients who may need to rely upon compensation if they are harmed by negligence are not in a position to make the decision about the types of indemnity that are available for the practitioner treating them, in their state. They are reliant on the state to protect their interests and to ensure that there are adequate provisions for indemnity, be it state indemnity or individual indemnity held by healthcare professionals. We believe, therefore, that it is in the interests of protecting patients that there should be an EU-wide requirement for mandatory regulated insurance or state systems providing equal certainty in respect of liability for clinical negligence claims. We do not believe there is room for any type of unregulated indemnity and all patients who are negligently harmed as a result of healthcare must be confident that they will receive compensation no matter in which state their treatment has been provided.

Q100 Chairman: We are really quite exercised about indemnity. You explain in your evidence that most doctors who are not NHS indemnified arrange their indemnity through one of the three medical defence organisations like yours, and unlike the other two MDOs the Medical Defence Union provides an insurance scheme in respect of claims for clinical negligence. Could you explain to us—we really do need to understand this and we do not—how the MDU model of indemnity functions, and what you consider to be its advantages and disadvantages compared with other models? Could you expand on your comment in paragraph ten of your written evidence which highlighted that the terms of the policy can hinder the right to assistance?

Dr Tomkins: I am a little confused by the reference to paragraph ten of our comments because in fact we have not made a comment that the terms of the policy can hinder the right to assistance. I think that may be a comment which comes from somewhere else. To explain our model of indemnity, MDU medical and dental members working in primary care and in the independent sector in the UK are provided with an insurance policy co-underwritten by SCOR Insurance (UK) Limited and International Insurance Company of Hannover Limited. The policy provides indemnity for negligence claims arising from our members’ provision of professional services in the UK. The policy has a limit of £10 million for each individual case and in the aggregate per policy year and the policy provides indemnity on a claims made basis. What that means is that our members are entitled to assistance under the terms of the policy for claims notified to the MDU while they hold the policy no matter when they arose providing that the member was a member of the MDU at the time of the incident. So if a member holds a policy today and reports to us an incident from ten years ago when he was a member of the MDU it will fall to the policy. Members are also covered for Good Samaritan acts they perform worldwide. In addition to the policy MDU members are entitled to seek indemnity on a discretionary basis for matters that fall outside the policy. Retired members or those who have left the MDU and no longer hold a policy are also entitled to seek assistance on a discretionary basis in respect of claims arising from any incident that took place when they were members of the MDU. Dental members do not need to rely on discretionary indemnity when they retire because they can extend their policy to provide cover for ten years after retirement or if they cease practising because of death or disablement. We believe that doctors should also have similar cover if they move provider or cease to practise for whatever reason and we would aim to provide this if mandatory insurance became a requirement in the UK. It is important because clinical negligence claims can be brought some years after the event which gives rise to the claim. Turning now to the advantages and disadvantages of insurance, the advantages of insurance are that they provide a contractual guarantee to pay, subject to clearly stated terms of the policy, whereas with discretionary indemnity there is no contract and there is no guarantee. Secondly, insurance is provided by companies which are regulated by the FSA for that type of business in the UK; MDU Services2 itself is regulated as an

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1 The comment the MDU made was “subject only to the terms of the policy”, which is addressed later in Dr Tomkins’s evidence to the Committee.

2 MDU Services Limited is the MDU’s subsidiary which is its operating vehicle.
insurance intermediary. That brings with it protection for the policy holder and so for the patient as a recipient of the compensation award. Protection comes through the Financial Ombudsman Service which, if there is a complaint or dispute about cover, can make a decision which the insurer has to adhere to. There is also the Financial Services Compensation Scheme that applies if an insurer is unable to meet its obligations so that the insured is not disadvantaged. None of those protections is available with discretionary indemnity. One of the key roles of the FSA is also to secure the right degree of protection for consumers and that includes vetting at entry, which aims to allow only firms and individuals satisfying necessary criteria to engage in these regulated activities. Once authorised it expects firms and individuals to maintain the standards it sets and it monitors firms and individuals to ensure that these standards are met and to enforce their requirements if that is necessary. It oversees the financial management of insurance companies in order to protect solvency margins and reduce the risks of things like, for example, capital flight. Another advantage is that if a doctor or a dentist is insured patients can benefit from the Third Parties (Rights Against Insurers) Act 1930 which provides them with a direct means of recovering compensation even if a doctor goes missing or fails to respond to the claim and that is not available with discretionary indemnity as a protection. The disadvantage of insurance is that it is more expensive than discretionary indemnity. The subscriptions our members pay need to reflect the insurance premium tax and the cost of complying with the FSA’s regulatory requirements, but regulation is, in our view, vital because it provides safeguards for our members and equally important, to any of their patients who claim compensation. It has been suggested there is a disadvantage by organisations providing only discretionary indemnity that an insurance policy might be restrictive but that is not the case. With discretion doctors or dentists can never know if they will be assisted and to what extent until they seek that assistance, and even while they are being assisted it is open to the defence organisation to limit or withdraw that assistance at any time and that is at the defence organisation’s absolute discretion with no regulatory oversight. No matter what comments may have been made about discretionary assistance provided to members in the past, the discretionary provider may not give any guarantee that assistance will be forthcoming and can only make the decision if it will assist and to what extent when the doctor or dentist asks for that assistance. There is nothing written down. Doctors and dentists do not know what they are entitled to receive nor whether they will receive it. Their absolute and only right is to seek assistance and to have that request considered. Those are the advantages and disadvantages of insurance.

Chairman: Thank you very much indeed, that is helpful. We look forward to your colleagues’ view of that. Lord Lea is going to ask you about EU countries and the comparisons, but before he does that can I just say that we may have misunderstood your comment in paragraph ten where you say, “In the UK, insurance is regulated and provides a contractual right to assistance, subject only to the terms of the policy”. Lord Kirkwood of Kirkhope: Can I come back to that in a moment?

Chairman: Do go ahead now.

Q101 Lord Kirkwood of Kirkhope: Have you ever refused a claim?

Dr Tomkins: Under the policy of insurance?

Q102 Lord Kirkwood of Kirkhope: Yes.

Dr Tomkins: We have and we have been to the Financial Ombudsman Service and the Financial Ombudsman Service determined in that case that we should pay the claim and we did.

Q103 Lord Kirkwood of Kirkhope: So the terms of the contract are discretionary.

Dr Tomkins: No, the terms of the contract are not discretionary.

Q104 Lord Kirkwood of Kirkhope: Could you give me more information about what the terms of the contract actually are. Give me some examples of the omissions on which you could found to deny the claim.

Dr Tomkins: I have brought a copy of the policy of insurance if that would be helpful. The aim of the policy is to provide insurance for the members for clinical negligence claims. There are certain circumstances in the policy where indemnity for a claim is not included and they might be things like a claim against a doctor by one of his employees which would generally fall to employers’ liability so that the contract specifies that an exclusion is a claim against a doctor by one of his employees, that is assuming, of course, that the employee is not also a patient (if the employee was putting a claim as a patient it would be covered by the policy); a claim which has something to do with the doctor’s premises; a claim which has something to do with pollution although, of course, that would not include patients who have suffered as

1 In respect of an unregulated indemnifier this could mean, for example, that funds subscribed by UK members are used to pay claims in another country.

2 The Act responds if the insured becomes insolvent or is made bankrupt and allows the claimant to claim direct from the insurer under the insurance policy.

3 The case in question was ultimately the subject of an arbitrator’s decision in the insured’s favour and the claim was paid.
a result of pollution who are being treated by the doctor. The exclusions in the policy are really exclusions which make it clear that this is a policy which meets clinical negligence claims.

Q105 Lord Kirkwood of Kirkhope: Could we take up the offer of the copy of the contract? You rely rather heavily on regulation of insurance companies. In the recent past there have been one or two failures of regulation. Are you confident that the regulation is available to insurance companies and gives the guarantee that you seem to be professing in the course of your suggestion that your system is better than anything else on offer?

Dr Tomkins: Yes I am confident that this provides the security for doctors which is better than anything else on offer. Does that mean that it is one hundred per cent safe in every circumstance? Clearly not because nothing is one hundred per cent safe in every circumstance, but that is why we have the Financial Ombudsman Service and that is why we have legal mechanisms in place to compensate the insured if an insurer is unable to meet its obligations and we have the third party rights against insurers. All of those are designed to protect the consumer. So the regulatory environment in as far as it is possible to do so protects the consumer whereas with discretion there is absolutely no oversight.

Q106 Lord Trefgarne: You referred to the Financial Ombudsman; there is an Insurance Ombudsman as well I think. Which one is it in this case? I once took a case to the Insurance Ombudsman and lost, needless to say.

Dr Tomkins: The case I referred to earlier was not a clinical negligence claim, as it happened, which shows that the Financial Ombudsman Service will always err on the side of protection of the consumer where there is an argument to do so. The redress of the insured who has a complaint against the insurer is through the Financial Ombudsman Service.

Q107 Lord Trefgarne: Not the Insurance Ombudsman.

Dr Tomkins: No.

Q108 Lord Lea of Crondall: It is often difficult to pin down exactly what we are asking in relation to the European Directive and perhaps you could indicate a general reaction to the draft Directive, to what extent the MDU model is similar to that deployed in other countries and what problems might be caused to the cross-border provision of healthcare by differing indemnity models across the EU. In that connection, in paragraph 14 of the notes signed by Mary-Lou Nesbitt, could you just enlarge on the last sentence which says “The UK (and Ireland) are the only Member States where discretionary indemnity is still available and we believe this is neither adequate nor appropriate”. That could be read perhaps in two different ways.

Dr Tomkins: There is a mix of indemnity provision throughout the EU depending on whether healthcare is provided by the state or the independent sector or both. The insurance provided to MDU members is similar to insurance that is mandatory in the majority of EU states where there is either a requirement for the healthcare institution or the doctors they employ to be insured or both. In Austria, Germany, Latvia, France and Slovakia it is, as we understand it, mandatory for doctors to have insurance. In the Czech Republic, Finland, Hungary, Poland and Spain there is a requirement for healthcare institutions and individual doctors to be insured. In Lithuania and Portugal there is a requirement for institutions to be insured and it is advised that doctors be insured because the institution can claim back from them any compensation payments it makes on their behalf. In Italy and Estonia insurance is voluntary. That is how we understand the situation to be. In a few states we have not found a requirement for insurance for doctors and those are Greece, Luxembourg and Slovenia. In Denmark and the Netherlands there is a state indemnity scheme and, as we understand it, individual doctors do not need to be insured but in Sweden, where there is also state indemnity, there is an additional requirement that doctors practising in the private sector are insured either personally or through the service companies in which they work. A minority of states allow discretionary indemnity; they are the UK, Ireland and Malta. If discretionary indemnity was considered acceptable for cross-border healthcare it would not meet the expectations of the majority of EU patients who expect certainty of compensation either because there is a state indemnity or the clinical institutions or individual healthcare providers are insured or a combination of any of these. That could give rise to difficulties so, for example, a German patient who was treated in the UK and negligently harmed by a doctor who was reliant only on discretionary indemnity might not be compensated if the indemnifier decided not to assist the doctor with the claim. Of course a German patient who had been treated and harmed in Germany by an insured doctor would not meet the expectations of the majority of EU patients who expect certainty of compensation either because there is a state indemnity or the clinical institutions or individual healthcare providers are insured or a combination of any of these. That could give rise to difficulties so, for example, a German patient who was treated in the UK and negligently harmed by a doctor who was reliant only on discretionary indemnity might not be compensated if the indemnifier decided not to assist the doctor with the claim. Of course a German patient who had been treated and harmed in Germany by an insured doctor would have received insured compensation. There is a real risk with discretionary indemnity that doctors and dentists may not be assisted and the patient will go uncompensated. In the United Kingdom while discretionary indemnity is currently provided to some doctors and dentists—including those who are members of the MDU—many other healthcare

6 If the insured is dissatisfied by the decision of the Ombudsman, he or she may pursue the complaint through the courts or, if the policy so provides, through arbitration.

7 The Insurance Ombudsman was brought within the Financial Ombudsman Service.
professionals actually have to be insured, their registration body requires them to be so. We have new regulations which came into force on 3 November\(^a\) which set out a requirement for all healthcare professionals, including doctors, who undertake assessments of mental capacity to be insured in respect of any liabilities that might arise in making those assessments. They have to provide evidence to the supervisory body that they have such insurance. Physiotherapists, chiropractors, osteopaths and optometrists in the UK have to be insured; their registration bodies require them to be. That leads to a further potential anomaly with cross-border healthcare. For example, if you had a German patient who sought treatment in the UK from an insured healthcare professional, like a physiotherapist or an optometrist, that patient could be sure of compensation if he or she was negligently harmed because these and other healthcare professionals are required to be insured. So it is inconsistent that patients would be subject to different levels of certainty in respect of compensation depending on which healthcare professional treats them or, if it is a doctor or a dentist, depending on which medical defence organisation they belong to. We believe that any indemnity requirement should make it clear that the indemnity must provide consistent cover for patients so they have the same guarantee that they will receive compensation no matter which healthcare professional they consult in another Member State. 

**Chairman:** I think you have just very helpfully answered the next question, Lord Trefgarne, you may want to follow something up after Lord Lea.

**Q110 Lord Lea of Crondall:** Was that thought fed into the consultation before the Directive?

**Dr Tomkins:** We have fed that into the EU officials who are dealing with it.

\(^a\) The Mental Capacity (Deprivation of Liberty: Standard Authorisations, Assessments and Ordinary Residence) Regulations 2008

**Q111 Lord Trefgarne:** Much of my question was covered by your response to the earlier question, but we are concerned that the legal framework under which all this will in due course be provided (following, as we assume, the implementation of the Directive) will mean that the legal basis in all Member States is more or less the same. Are you content that that is what will indeed emerge from this process?

**Dr Tomkins:** I think that there is a difficulty with the wording because Article 5(1)(e) allows indemnity to be provided by state schemes’ insurance which are the only means in most of the Member States, but as it stands at the moment it could be interpreted as allowing discretionary indemnity to be used for clinical negligence claims because the phrase that concerns us is "systems of professional liability insurance or a guarantee or similar arrangement, which are equivalent or essentially comparable as regards their purpose". We understand that the draft Directive is phrased in this way because of the need to encompass state indemnity schemes so it did not have discretionary schemes in mind, it had state indemnity schemes in mind with this wording. We do not believe discretionary arrangements are similar or essentially comparable because they do not provide a guarantee of indemnity and are not subject to regulation. The courts in the UK and Ireland confirm that discretionary indemnity is not insurance and that discretionary indemnifiers are not subject to the law relating to insurance regulation. We do think that the draft Directive should be amended in the interests of patients and healthcare professionals so it is clear that the treating states are required to ensure compensation for claims in respect of treatment in their territory through state indemnity or indemnity insurance underwritten by regulated insurance companies.

**Chairman:** What is clear for everyone is that we do need absolute clarity.

**Lord Trefgarne:** It does not follow that it all has to be the same, does it?

**Chairman:** No, not the same; it has to be clear, I would have thought.

**Q112 Lord Trefgarne:** Clear but not necessarily the same. I am much in favour of the policy of subsidiarity. Maybe a one size fits all is not the best way.

**Dr Tomkins:** I think that is right but, on the other hand, we have, for example, in the Non-Life Directive on insurance a move towards harmonisation of insurance arrangements throughout the EU and the only way to achieve certainty and clarity for the patient is to have a clear contract which the patient understands.
Q113 Lord Trefgarne: Harmonisation is one thing, but identical policies is another.

Dr Tomkins: I do not think identical policies are viable because the risks and the judicial systems and the compensations systems in the different territories are different and the policy applying in any particular state needs to take that into account.

Chairman: I would advise the witness that Lord Trefgarne is a great defender of subsidiarity.

Q114 Baroness Young of Hornsey: I wonder if you could give some indication of the current numbers of patients who have made claims as a result of having treatment across different borders. Is there any kind of sense of what that currently stands at. I am trying to get the grip of what is currently happening and what then might change as a result of any Directive?

Dr Tomkins: No, I do not have any numbers of claims in relation to patients who have had medical treatment outside their home state but I understand that the number of patients actually receiving treatment is relatively small, fewer than one per cent of the number of patients being treated. I do not imagine that the number of claims arising from those would currently be large but, of course, for various reasons we can expect the number of patients being treated abroad to increase in the future and therefore I think the problem needs to be addressed before that happens.

Chairman: Of course; I am just trying to get a benchmark.

Q115 Baroness Neuberger: You were very clear that basically patients ought to be able to get compensation in the host country wherever they have the treatment and you have obviously fed that in to the officials and there has not been thus far, as far as we can see, a lot of response. Are you concerned that this is going to be a major obstacle in allowing patients to be more mobile in Europe? Do you think it is going to stop people travelling? Do you think the EU should take it seriously from that point of view?

Dr Tomkins: I think it might stop people travelling, perhaps not initially but if circumstances arise in which there is an uncompensated patient then the problem will come to the fore and may well be a deterrent to free movement of patients across boundaries.

Lord Trefgarne: We are talking about microscopic numbers, are we not?

Baroness Neuberger: We are at the moment but it may change.

Q116 Baroness Morgan of Huyton: Obviously the situation is complicated already and, picking up on that last point, I suspect most people now do not know what the position is. Moving forward, if this Directive were to come into operation, what sort of information do you think should be given and who should be responsible for making sure that patients are informed properly?

Dr Tomkins: We believe the Member States should be responsible for provision of information about redress and compensation within that state.

Q117 Baroness Morgan of Huyton: Is that the governments or the health practitioners in different states?

Dr Tomkins: I think there may be an argument for having a body whose function it is to provide this information and having such a body in each of the EU states who are charged with providing information about the delivery of healthcare, the quality, the safety and the methods of complaint and redress within that state so that patients who are going to go across borders for healthcare have a reference point; they have one in their country and they know that each EU state has that equivalent body in their country.

Q118 Baroness Morgan of Huyton: I do not really quite follow that. Surely you are not suggesting that in Britain we set up an additional body that only does that?

Dr Tomkins: That is one way of looking at the problem, or the responsibility might devolve, for example, to the Department of Health. I think that is a matter for those who decide how the information should be disseminated. What is key is that patients should know where to go and that the Member States should be providing that information which is clear, accurate and up-to-date for the patients so that they can make an informed decision.

Q119 Chairman: What is absolutely clear again is that patients will fall between a variety of different organisations. I know this is not your area, but do you have a preference? Do you think independence is important in giving information?

Dr Tomkins: Yes, I do think independence is important in giving information. If I were a patient and I knew that there was a body in my territory that I could go to and that every other EU state had such a body too, then I think that might help me to find out what I needed to know.

Chairman: We are very grateful to you for getting through this. We are going to have to change over right now because of the timing. Thank you, and thank you to Dr Stewart for supporting you. You will come back at the end if you so wish. We will now move on to the MPS.
Memorandum by the Medical Protection Society (MPS)

ABOUT THE MEDICAL PROTECTION SOCIETY (MPS)

1. The Medical Protection Society (MPS) is the leading provider of comprehensive professional indemnity and expert advice to more than 250,000 doctors, dentists and other health professionals around the world. We have over 100 years’ experience of the medicolegal environment and operate in 40 countries around the world—within the European Union we operate in the United Kingdom, Republic of Ireland and Malta. This gives us a unique perspective on patient safety. In the United Kingdom our membership consists of around half of all doctors and three quarters of all dentists.

2. As a mutual, not-for-profit organisation, owned by its members, we provide help for our membership, on a discretionary basis, with legal and ethical problems that arise from their professional practice. This includes clinical negligence claims, complaints, medical council inquiries, legal and ethical dilemmas, disciplinary procedures, inquests and fatal accident inquiries. In the last five years we have dealt with around 11,000 clinical negligence claims; 18,600 complaints; 1,680 inquests; 3,700 medical and dental council inquiries and 850 disciplinary hearings in the UK alone. We offer a medicolegal advice line, with 24-hour access for emergencies, to support members in resolving dilemmas and promoting good practice.

3. Patient safety has always been intrinsic to MPS and one of our strategic objectives is to help members through education to prevent avoidable harm to patients. We offer comprehensive education and risk management programmes, including lectures at medical schools, hospitals and other healthcare organisations; publications focusing on common pitfalls of practice and promoting best clinical practice; and a risk management consultancy, advisory and training service.

INTRODUCTION

4. MPS welcomes the proposal for a directive on the application of patients’ rights in cross-border healthcare. We believe that a community framework that provides for high quality healthcare services and lends greater clarity about the application of community law to cross-border patient mobility is an important and necessary development.

5. The Committee’s inquiry presents a welcome opportunity to address some of these challenging issues. Patient mobility raises a number of complex points relating to redress for patients and access to justice. Our response focuses on the question of the practical impact of the proposals, particularly the availability of redress when patients suffer avoidable harm.

ACCESS TO REDRESS

6. The overwhelming majority of healthcare professionals deliver excellent care to their patients every day. However, medicine is not an exact science and sometimes patients suffer avoidable harm as a result of human error and systems failures in treatment.

7. It is important that patients receiving medical and dental treatment in any member state have access to information about professional standards and complaints mechanisms. They must also be confident that they will have access to redress and compensation where appropriate, if they are injured as a result of negligent treatment.

8. MPS supports the principle that the body that commissions the healthcare treatment is responsible for ensuring that adequate and appropriate indemnity is in place.

9. The differences between legal systems within the European Union pose challenges for doctors and patients alike. We endorse the principle that a patient who has suffered harm as a result of medical treatment must be entitled to seek compensation through the courts, both in the country where the healthcare treatment was provided and their country of domicile. However, it is important to recognise that the differing legal systems can pose obstacles for patients seeking compensation and healthcare professionals responding to allegations.

10. MPS has experienced practical difficulties when representing doctors or dentists who have been the subject of legal action in one country about treatment they provided in another country within the EU. For instance, if a patient brings a claim in their country of domicile but received treatment in another country within the EU, there can be difficulty with the availability of witnesses and with collecting evidence. The jurisdictional issues are complex and we would like the European Commission to consider these issues.
11. Where a patient receives medical and dental treatment in another country, it is paramount that the patient is able to secure compensation if something goes wrong. Failure to ensure this fundamental legal principle would undermine patient mobility. This should be as seamless and simple as possible and adequate mechanisms to ensure delivery of compensation should be put in place.

12. We wholly support the requirement in Article 5(1)(e) that member states must ensure healthcare professionals hold insurance or other forms of comparable indemnity. The construction of Article 5(1)(e) encompasses both insurance and other equivalent arrangements, such as discretionary indemnity.

13. We believe that this wording accords with the principle of proportionality and reflects moves made by the UK to make professional indemnity compulsory for doctors and dentists.

UK CLINICAL NEGLIGENCE CLAIMS

14. Briefly, the way in which clinical negligence claims in the NHS are handled differs between primary and secondary care. In secondary care, the National Health Service Litigation Authority (NHSLA) runs the Clinical Negligence Scheme for Trusts (CNST). This scheme has handled all clinical negligence claims against member NHS bodies in secondary care since 1 April 1995. In contrast, in primary care, MPS and other medical defence organisations (“MDOs”) such as the MDU and MDDUS, in return for a subscription fee, offer legal representation and either discretionary indemnity or a policy of insurance, or a combination of both against the cost of clinical negligence claims brought against independent contractors such as GPs, dentists and private healthcare practitioners.

15. The three traditional mutuals, MPS, MDDUS and the MDU, have been providing indemnity to doctors and dentists in the UK for well over 100 years. MPS and MDDUS offer discretionary indemnity. The MDU offers a combination of insurance and discretionary benefits.

16. Legislation, after extensive consultation and debate in both Houses in 2005 and 2006, was approved to require all medical and dental practitioners to hold adequate and appropriate indemnity.\(^1\) The legislation provides for a policy of insurance, discretionary indemnity, or a combination of the two. The GMC and GDC are currently drawing up rules to put compulsory indemnity into practical application.

17. In relation to professional indemnity, the UK is more advanced than some other European countries because it has already made professional indemnity compulsory. However, while parliament has clearly approved the current system of discretionary indemnity or insurance for healthcare professionals, we recognise that discretionary indemnity is likely to be a concept that is not familiar to a number of Member States. We support the wording of the current provision in Article 5(1) and would like to see this maintained, along with recognition by the European Commission of the different forms of indemnity available to doctors and dentists.

18. We believe that discretionary indemnity is the best protection for doctors, dentists and their patients. The discretionary approach allows the flexibility to offer assistance with new or unusual problems that arise as the practice of medicine and dentistry develops.

19. MPS indemnity is comprehensive. There are no financial caps and it is offered on a claims incurred basis. This means that all claims that arise from any period when they were in membership fall within that cover even though the claim may be reported many years after they have ceased to be a member— for example, if they retire, move away or take a career break. In the UK, we believe that all policies of insurance in medical malpractice are on a claims-made basis. The biggest potential problem is claims-made indemnity without run-off provision. Claims-made cover without run-off only responds if the doctor is a member or policy holder when the claim is brought. Practitioners with claims-made insurance, who stop working for any reason and do not maintain cover, may be left exposed. We are concerned that, with increasing mobility of healthcare professionals, doctors or dentists from other European countries may be relying on their European insurer from their previous employment to provide their indemnity cover.

20. MPS has never exercised its discretion to withhold or withdraw indemnity from a member facing allegations of clinical negligence, when he or she had provided bona fide medical treatment and paid the appropriate subscription at the relevant time. Consequently, no patient entitled to compensation has ever been left uncompensated as a result of MPS exercising discretion. On the contrary, we can provide numerous examples where MPS has exercised its discretion positively and helped members and their patients where a contract of insurance would almost certainly not have responded.

\(^1\) The Dentists Act 1984 (Amendment) Order 2005 and the Medical Act 1983 (Amendment) and Miscellaneous Amendments Order 2006
21. Indemnity is only as reliable as the organisation providing it. In the UK, the medical and dental professions are extremely fortunate in having had an unbroken period of more than a century, during which mutual, not-for-profit organisations have provided them with discretionary indemnity and a range of other support and advisory services. Over that same period, various insurance companies have entered (and left) the medical/indemnity market here in the UK, just as has happened in other parts of the world.

22. We understand the European Commission, in conjunction with Member States, plans to develop interpretive guidelines to facilitate the implementation of Article 5(1). We support the European Commission’s view that it is for Member States to determine the nature and modalities, and ensure the accessibility, of mechanisms for patients to seek redress and compensation if they suffer harm as a result of receiving cross-border healthcare. A more prescriptive approach would be detrimental to patients and healthcare professionals in the UK and would, in our view, undermine the principle of proportionality.

23. We do, however, suggest the European Commission explores whether high level principles and guidelines about the quality and availability of redress would be appropriate.

Conclusion

24. We recognise that redress and access to compensation is one small part of a much larger debate on many complex issues around the delivery of cross-border healthcare. Nonetheless, we believe it is an important issue; we would not like to see a UK citizen who has been harmed negligently in another EU country denied compensation because of a jurisdictional issue or lack of provision for professional indemnity or insurance.

25. We recognise that while discretionary indemnity, provided by mutual not-for-profit organisations, has protected doctors, dentists and their patients in the UK for over 120 years, it may not be a familiar concept to some other countries within the European Union. We agree that, in accordance with the principles of proportionality and subsidiarity, the onus should be on Member States to ensure healthcare professionals hold adequate insurance or other indemnity.

8 October 2008

Examination of Witnesses

Witnesses: Mr Tony Mason, Chief Executive and Dr Stephanie Bown, Director of Policy, Medical Protection Society, examined.

Q120 Chairman: Could I ask you to state your names and titles for the record and then say if you want to make a short opening statement.

Mr Mason: My Lord Chairman and members of the Committee, my name is Tony Mason and I am the Chief Executive of the Medical Protection Society.

Dr Bown: I am Dr Stephanie Bown; I am Director of Policy and Communications in the Medical Protection Society.

Mr Mason: I would like to make a short opening statement. First of all, thank you for inviting us to give evidence this morning. I would like to start by saying that MPS welcomes the development of a community framework that provides high quality healthcare services and which lends greater clarity about patient and community law to cross-border healthcare issues. We also fully support the requirement that patients have access to compensation should they suffer negligent harm arising from cross-border treatment. We are particularly pleased that article 5(1)(e) of the proposed Directive supports the view of the UK Parliament that various forms of indemnity, not just insurance, are acceptable. During 2005 and 2006 both Houses of Parliament in the UK debated the issue of insurance and discretionary indemnity and after extensive consultation legislation was enacted that requires all medical and dental practitioners to have adequate and appropriate indemnity in this country. The legislation provides for a policy of insurance or discretionary indemnity or a combination of the two and currently the General Medical and Dental Councils are drawing up rules to put all this into place. The wording of article 5(1)(e) is therefore very important in recognising the core principles of subsidiarity and proportionality that are enshrined in the original European treaty. The members of this Committee will have seen from my CV that before joining MPS as their Chief Executive I was a consulting actuary and for nearly 25 years I specialised in the field of clinical negligence. My clients have involved doctors’ mutuals, governments and insurance companies, and I have advised on all the different types and ways and methods of actually providing medical negligence indemnity. Although I fully support the principle of giving individuals the freedom of choice—a choice between insurance and discretionary indemnity—I am personally convinced that discretionary indemnity is the best form of cover. In my view the fair and appropriate compensation of victims of medical negligence is far too important for governments to leave in the hands of insurance
companies. I believe that the best approach is for governments to work closely together with the medical and dental professions to ensure that it will be a long term and sustainable solution. The insurance industry actually has a very poor record when it comes to medical negligence and in my career I have seen more than a dozen examples of insurance companies that have entered a market when conditions look good only to withdraw when they see claims rise and profits fall. Perhaps the most infamous case was that of St Paul which was an American insurer and the largest in the world (the largest indemnifier of medical negligence cover in the world) which in 2001 announced that with immediate effect it was withdrawing from the market and it left 750 hospitals and 115,000 healthcare professionals in America without on-going cover. It also operated in other countries around the world and its withdrawal was quite devastating at the time to some of the healthcare professionals involved. The Medical Protection Society was formed by doctors and dentists in 1892 as a mutual company and over the last 116 years it has grown to having more than a quarter of a million members around the world with half the practising doctors in the UK and two-thirds of the dentists who remain owners of the company. Its initial ideals today are the same as when it was established, that is to protect the financial interests and reputations of the medical and dental professions, to improve patient safety through education and risk management and, equally importantly, to ensure that patients who have suffered as a result of clinical negligence receive fair and appropriate compensation. In all the history of MPS there is no example of MPS exercising its discretion so as to allow a patient to go uncompensated where that patient has been found to have suffered from the medical negligence of one of its members who was entitled to assistance. That is the true strength of discretionary indemnity. It is a system that works with a proven track record.

Q121 Chairman: You have explained in great detail how your model works. Can I do what I did to your other colleagues, you have told us its advantages but what are its disadvantages? You say there has been no instance of a patient going uncompensated where that patient has been found to have suffered from the medical negligence of an MPS member who is entitled to assistance. Can you tell us if there are any instances where indemnity might be withheld?

Mr Mason: A member, a doctor say, who has a claim brought against him by one of his patients applies to MPS for assistance in the same way that a member of a trade union would apply for assistance. The first thing we do is to check that the individual was a member of MPS at the time the incident took place because it is a very important part of our cover that we are occurrence based. This means that we will indemnify a doctor if he was a member at the time the incident took place even though he may have retired, left or even died in the meantime. If the individual was not a member at that time then we obviously would not give cover. The problems that are sometimes encountered—not that often—are when a doctor has, say, said that they operated in one area of medicine when, in fact, they were giving treatment to a patient in a different area of medicine where they should have paid a significantly higher subscription to us. In those circumstances we will normally require that member to pay us the back subscriptions. What we do not like to have happen is to allow patients to go uncompensated. When it comes to claims we have looked and there are no examples of where we have allowed patients of a member entitled to assistance to go uncompensated. Where MPS tends to exercise its discretion sometimes against the doctor is not related to claims of negligence and patients, it may be to do with disciplinary hearings or other matters occasionally where we feel that the doctor wants to pursue something way beyond any chance of success. But that in itself is rare. All our decisions are subject to appeal at MPS’s Council which is an elected body of doctors, dentists and other professionals—lawyers, accountants, actuaries, insurance specialists—and they always have the right to appeal there. Basically all our members have a right to ensure that any exercise of discretion has been done fairly and properly. At the end of the day there really are no drawbacks to the system: only the perception that we may not cover.

Q122 Chairman: The previous witnesses gave us the impression that it felt unclear and insecure. What would be your response to that?

Mr Mason: There has to be a level of trust with discretion and really it is the track record that is really important. I do not actually believe that knowing a doctor has a contract of insurance gives any particular guarantee or comfort; it does depend on the wording of that contract and the exclusions. Every insurance contract will be different in the different countries. In various countries in Europe there will be maybe seven, eight, ten, twelve different insurance companies offering contracts of insurance, all of those will be different, there will be different exclusions. One of the common reasons why insurance companies will turn things down is the non-disclosure or inaccurate disclosure. I am sure everybody in this room either themselves or will know somebody who has had an insurance claim which has been turned down. They considered it to be a valid claim but it was turned down because

9 Other matters might involve criminal charges such as indecent assault outside a clinical setting; civil claims such as defamation claims; personal misconduct; and employment issues such as discrimination.
insurance companies stick to the letter of the policy. That is correct; regulators insist that insurance companies stick to the letter of the policy because otherwise they would potentially have liabilities that the regulators do not know about. So it is a fundamental part of insurance.

Q123 Lord Kirkwood of Kirkhope: You will have to look at this from our point of view; this is not a beauty contest. You are both very helpful at helping the Committee understand; all we are trying to work out is how we get the best protection in this European Directive. I think we are all on the same side in that. For the sake of completeness, you must have some sort of agreement, could we ask similarly that we see what it is that you offer as a template example that could be made available.

Mr Mason: We are very happy to let you see our memorandum and articles for the MPS and give you all the details. The key thing is that we cannot guarantee to pay. The real strength of discretion is that when you get odd circumstances—something unusual, something which falls outside an insurance contract—we can still help and assist. Our main aim is not just the individual doctor, it is the reputation of the medical profession and it is not good for the medical and dental professions to leave any patient uncompensated.

Q124 Lord Kirkwood of Kirkhope: You referred to St Paul in 2001 in America, but the MDU tell us there was an example of a failure in Australia in 2000, a discretionary indemnifier. What do you say to that?

Mr Mason: That is actually my specialist area because I had five clients in Australia at the time. There were seven medical defence organisations in Australia, six of them provided discretionary cover, one of them provided a contract of insurance on a claims made basis with discretionary additions. That is exactly the same model as the MDU. It is that company that got into difficulty and it was the insurance company that actually had the problem, it was not with the discretionary indemnifier. The directors of that insurance company went to the courts and asked for provisional liquidation and in fact it was turned down. They did not actually need it but they went back again because the directors could not get directors and officers insurance. It is quite a complex matter.

Q125 Lord Kirkwood of Kirkhope: I am beginning to wish I had never asked the question.

Mr Mason: The actual discretionary organisations in Australia were all sound and continue to be sound. Australia is a prime example of what is wrong with insurance actually.

Q126 Lord Kirkwood of Kirkhope: You say you have a council of the good and the great to look at all this stuff but you have no right of legal appeal if all that fails.

Dr Bown: We have a legal obligation to exercise discretion fairly and not capriciously and there is a remedy for a member to challenge a decision to withhold discretion. They have a contractual entitlement to have the exercise of discretion exercised fairly.

Lord Trefgarne: I was going to come to exactly that point which Lord Kirkwood has made. The liability of a negligent practitioner is not confined to the insurance cover or other cover that he has secured; it is a question of fact decided by law. If I feel that a practitioner has been negligent and I get a judgment against him for X thousands of pounds, if his insurance cover provides payment for that then that is fine but if not he is personally liable and that is that.

Chairman: I think the answer is yes and Lord Trefgarne has answered his own question. Can we move onto Lord Lea and Europe now?

Q127 Lord Lea of Crondall: You heard the interchange a few moments ago with the MDU on this broad area. You seem to be reasonably happy about the draft Directive as far as I understand it. Could you comment on the problems that may be caused by different indemnity models and, in that connection, could I ask how you do your representations in Brussels? Do you get together or is it under the umbrella of the BMA or something? Is there a European body that does the negotiations or input or whatever you like to call it.

Mr Mason: The problems that I see are that the insurance policies are all different; there are some very good insurance policies out there. In some countries you can actually buy an occurrence based insurance but most insurance contracts are claims made in Europe which means that if a doctor ceases to pay his premium and then moves overseas or returns to another continent, if they have not taken out what is called run-off cover, patients are potentially going to be exposed because there is no doctor there to actually sue. The main issue is really exclusions or conditions in the contract of insurance. Just putting one thing into perspective, the chances of a patient going uncompensated as a result of the indemnity arrangements of a doctor are very small, miniscule. There will, however, every year be thousands of patients who go uncompensated because they either did not know they were subject to harm or they knew, but decided not to take it forward, or they cannot find lawyers who will represent them, or the Legal Aid system is not good enough, or the causation is a bit dubious and they cannot prove what is actually a valid case, or through the inexperience of their solicitors. There are a lot of
reasons why patients go uncompensated and we are actually talking here about the possibility that over a very long period something might happen that has not happened in the past. Compared with all the other problems of trying to ensure proper healthcare we are talking about a really, really minor point. The real issues are that in a lot of the European countries it is actually very difficult to bring a claim against a doctor. My major concern for you really is that there will be patients going from the UK to other countries who will find it very difficult to bring a claim. It has nothing to do with the indemnity arrangements for the doctors concerned, it is just that the legal system does not make it easy to bring claims and I think that is one of the important issues.

Q128 Lord Lea of Crondall: I asked you about the structure of your representational body in Brussels, can you say a bit about that?
Dr Bown: MPS undertakes its own representation and we make arrangements to meet with and speak with MEPs. We started on this with the Services Directive which initially included healthcare and then the healthcare component was dropped. So we do have links with MEPs but we lobby and we do our relationship building as an independent, stand alone organisation.

Q129 Lord Lea of Crondall: Are there sister bodies around France and Germany that you get together with?
Dr Bown: No.
Chairman: We are going to have to move on in view of the time if that is all right with you. Lady Young, you are going to pursue any other remaining bits about this legal framework.

Q130 Baroness Young of Hornsey: Uncovering all these complexities is very interesting particularly as we understand that a relatively small—miniscule is the word that keeps being used—number of people might be affected, nonetheless for those individuals it is quite high stakes so it is quite important that we clarify it. In terms of your interpretation of the proposed legal framework, how do you interpret it? What obligations do you feel it is placing on each Member State? We have had this debate about harmonisation or is it making things similar or is it making things the same, how workable is it and how might the provisions be clarified to your satisfaction?
Dr Bown: Our interpretation is that the legal framework is setting out the responsibilities on Member States for ensuring that these patients’ rights are accessible. There is also the emphasis that it is for individual Member States to decide how they will achieve the purpose of protecting patients. In our written submission we based our suggestion on the system in the UK whereby the commissioner of healthcare is responsible for ensuring that there is insurance indemnity in place. Having really reflected on this at length, and looking at the potential complexity of the bringing together 27 different Member States providing treatment to patients from 27 countries, we do not think that is workable and we do now completely accept the proposal in the Directive that it should be the obligation on the Member State of treatment to ensure that those providing the treatment hold professional liability insurance or indemnity. We see that it is the obligation on Member State of treatment not only to ensure that there is appropriate indemnity in place but also to ensure that there are mechanisms for redress and compensation. Moving on to your question about how workable this is, we do have grave concerns about how workable it is going to be. If you look at the situation in the UK we have a position, as has been explained, whereby doctors and dentists have an obligation to have professional indemnity in place and we do not know whether that applies across different European states. It is terribly important if you think about our UK patients that when they travel to other Member States they must have confidence that they are going to have access to redress and compensation. Similarly in the UK we have a well-developed complaints system and a well-developed system for access to redress. Although sometimes it catches its critics it is well developed. We are not confident that such similar mechanisms of redress are necessarily currently available within other Member States. There is a whole thorny area of what happens with split care where you have your original treatment in France and then you come back and have follow up treatment perhaps in the UK and there may be deficiencies in both sites, and that again is a potential for complexity. In terms of clarification of the provisions certainly we would be looking for absolute clarity and unambiguous wording about who is responsible for the delivery and funding of aftercare and for where the indemnity should lie. We know that there are interpretive guidelines to be developed and they will have a crucial role. Then we have a very grave concern about the definition of harm in Article 4 which defines harm as “adverse outcomes or injuries stemming from the provision of healthcare”. We believe that essentially this introduces a no fault compensation which would be a fundamental departure for the UK. If I could illustrate what that might mean, for instance a patient with diabetes we know is at greater risk of potential post-operative wound infection. They are warned about that, they accept the risk, surgery is performed with all due care but the patient is unfortunate enough to get a known, recognised complication of a wound infection, the wound might break open, they are in hospital for much longer, they have suffered harm as a result of treatment. Under
the current clinical negligence that would not be compensatable and we do believe that the terminology of harm should refer to negligence.

Q131 Baroness Young of Hornsey: Is that under clinical negligence in the UK?
Dr Bown: Under our system yes; it would have to be avoidable harm as a consequence of sub-standard care. So you would need to have deficiency in care which causes or materially contributes to the patient's harm.
Chairman: It is a question of clarity of wording, that is absolutely crucial. We need to move on because of the time. Lord Wade, are there other things you want to ask about the differing legal system?

Q132 Lord Wade of Chorlton: You have dealt with a lot of the questions that I was going to ask on the question of differing legal systems within that answer but I would just like to follow on one or two things. Could I just say that I have suffered from exactly the point that you made, that being diabetic I have had some very serious problems and there was nothing I could do about it, I just had to solve it myself. Mr Mason mentioned the fact that the legal system could be so different than legal systems in other areas, and that is an interesting point which he might be able to talk about a bit more because that depends on different legal systems not so much on the question of redress and compensation but on the actual way of dealing with the matter from the beginning. The other point I would also like to make is that you referred to the fact that most people treated elsewhere other than their home country will make the decision to move there. You may well be ill but did not intend to be treated in the other country but you happen to be taken ill there. Clearly in those circumstances it is much more difficult to actually find out the legal process, is it not? Is that not an issue that we will need to be looking at as well?
Dr Bown: I think the circumstances of what happens when you fall ill on holiday are outwith this particular Directive and would come under the E111 mutual recognition of treatment. We do see the potential for a great confusion when you have 27 different states with potentially multiple different systems and, in addition to that, we have to consider for our patients language barriers, different meanings and interpretations. There are challenges with regard to accessing evidence if you go back to your state of domicile, accessing the medical records, getting witness statements and even access to professional advice and representation. We see Article 12, which provides for a national contact point in the Member State of affiliation, as being the potential way of ensuring that there is comprehensive, accessible and consistent information available for patients in their state of domicile but, similarly, there must be an equal obligation on the treating Member State to provide information about what treatments are available and what mechanisms for redress there are.

Q133 Baroness Gale: It seems to me that the big thing is information. The information you say should cover access, redress and compensation. How do you think this information can be provided and who should be responsible for its provision? You talked earlier about a national contact point, could you say more on that?
Dr Bown: Certainly I think that patients will want information that is accessible and consistent in terms of quality, scope and being understandable. Therefore we would suggest that having it provided at a national level so there is consistency is probably the right way. However, we do not underestimate the size of the task and the potential cost for doing this, but we owe it to patients to make sure that the choices they make are informed choices. There was one other point that I thought might be useful to mention which is that in January 2009 an EC regulation called Rome II is coming into effect. It is our view that it is better for patients that there should be clarity about the country in which they should pursue their redress. We think it is better that that should be the provider country. Rome II, which comes into effect in January next year, will apply the basic rule that where the parties are domiciled in their relevant jurisdiction—the claimant, patient and respondent doctor or organisation—the governing law will be the law of the country where the damage occurs. In the vast majority of cases that would be the Member State in which the treatment is being given and that, to us, would reinforce the value of having a consistent mechanism whereby the claim is brought in the country of treatment.

Q134 Chairman: I absolutely see the logic of that but if you are a patient and you have gone home how do you think that that patient can then pursue the difficulties in another jurisdiction?
Dr Bown: That comes back to the role of this national contact point which is going to be hugely important. Mr Mason: There are some real issues in countries that have no-fault compensation—the doctors will not have any indemnity cover. You can only really deliver the proper compensation in the country where the treatment took place. This is what we have actually concluded.
Dr Bown: That must therefore be a critical component to the decision that the patient makes about where they go for their treatment.
Q135 Baroness Gale: They would need really to have all that information before they have their treatment.
Dr Bown: Absolutely.

Q136 Baroness Gale: That is the important thing, that they know at that point what is going to happen if they are unfortunate enough that something goes wrong.
Dr Bown: Indeed, and whilst we very much welcome the role of general practitioners as being gatekeepers for access to cross-border healthcare we think it is of absolute crucial importance that they should not be held liable for the quality of the information that should be available at a national level.
Lord Wade of Chorlton: If a patient decided to travel to another country for a particular operation and he was aware of the difficulties, could he then take out an insurance in this country against any eventuality of going wrong?

Chairman: You can take out a general insurance for anything.
Q137 Lord Wade of Chorlton: Is there an insurance company that deals with that sort of thing?
Mr Mason: I suspect you could certainly take out personal accident insurance. There will be insurances out there and I suspect it may be an area that could be developed. I am not sure that there are any that are specific to that risk but you could take out insurances which would cover you for actually being off work or incurring some serious harm.
Lord Wade of Chorlton: It could be a lot more expensive in one country than another. That might be a good thing to find out.
Chairman: I think we might want to pursue that aspect, Lord Wade. Could I ask the other witnesses if they would like to join us again. Time is moving on but we have two or three minutes in which to pursue any remaining matters.

Examination of Witnesses
Witnesses: Dr Christine Tomkins, Deputy Chief Executive, Dr Hugh Stewart, Head of Case Decisions, Medical Defence Union, Mr Tony Mason, Chief Executive and Dr Stephanie Bown, Director of Policy, Medical Protection Society, recalled.

Chairman: We only have a very few minutes left and we are very grateful for all the work you have given us so far. It is an area where you can see we have a lot of interest and there is a lot of clarity to be sought if this is going to work in any way.

Q138 Lord Lea of Crondall: In most walks of life in the analogous situation there would spring up links between the French and the German set up or the Spanish and the British set up and you would have colleagues who would have regular contact with each other and there would be the emergence of some sort of forum where you get to know your colleagues in Poland or wherever may be. Take Poland as an example, do you never meet anybody or have I misunderstood?
Dr Bown: What I omitted to make reference to is the Physicians Insurance Association of America which is a group of a number of healthcare indemnifiers and insurers which do indeed come together and share experience.
Dr Tomkins: If I could add to that perhaps more relevantly there is an organisation called Europa Medica which does exactly that. It is an organisation of insurers of doctors and hospitals in Europe. The MDU is a member of that.

Q139 Lord Kirkwood of Kirkhope: You have been very helpful this morning. Is this worth doing? In your evidence you have both shown enthusiasm for establishing this right, it is a right for people to exercise if they wish to do so, but the more you look at this the more complex it becomes. Is it worth the candle?
Dr Tomkins: Yes, I believe it is worth the candle because, as we have an increase in tertiary centres of excellence, there is going to be an argument for people crossing borders to go to tertiary referral centres; for people who have rare conditions there will be specialist centres across borders; for people who live near borders there will be hospitals that are across the border to which they need to go. Then there is the question of people who find themselves in another EU state from their home state and who fall ill there. They need to know what the arrangements are. Yes, there should be free movement of patients across borders. I anticipate that there will be more of it as time goes on and if there is then patients need to be clear of what they are going to get.

Q140 Chairman: So what you are saying is that choice and availability is worth working hard at getting clarity in these other areas. I think Lord Kirkwood is wondering how easy is it going to be to get clarity in your particular area. I think we feel even more doubtful; this is not your fault, we have found it very helpful having heard your evidence.
Dr Stewart: I think it is worth emphasising that the preamble to the draft Directive makes clear that there are European Court judgments which say that you can move in this way and that is why the draft Directive is there. It is not a question really for us as
to whether a patient should be able to move across borders; they are able to move across borders and that is now a matter of European law. This is clarifying the means in which they can and the protections for them and the main part of our evidence today was that one of those protections is the issue of the nature of any indemnity provisions for them. I wonder if I might make one brief comment following our colleagues’ comments. Stephanie Bown pointed out that there are risks for UK patients who may go abroad in terms of them getting indemnity. Lord Trefgarne suggested that the principle of subsidiarity was important and that not all countries require the same insurance requirements but what the European Union can do more effectively than individual Member States is to ensure that as a minimum there is some guarantee of a right for patients who are harmed by clinical negligence in a European Union country to obtain compensation. Mr Mason said that with discretion there is no guarantee and the point I wanted to make is that this is not about the MDU and the MPS, it is about discretionary indemnity as opposed to contractual indemnity by insurance. I do not think it is enough to say “trust us” or “look at our past record” because it is not about one individual supplier, it is about whether UK patients may go to other European Union countries, be harmed and be reliant only on discretionary indemnity where the doctors only have a right to request assistance but there is no guarantee that any indemnity will be forthcoming. Although, as Lord Trefgarne said, you can take action against individual doctors, but if your claim is for £5 million because you are brain damaged as a result of negligence the doctor is unlikely to have sufficient funds.

Mr Mason: I think it is important considering that the patients do have the right to go between countries. It is not going to be a simple matter. It really is, I believe, up to each country to decide what is adequate and appropriate indemnity. The General Medical Council and the General Dental Council have, over the last year, been considering the issues; there are some very, very complex issues. It is not just indemnity; some doctors are covered by their employer; some by government, some by universities, some by schools. Some of the hospitals do not insure, they carry self-insurance. There are a lot of very, very complex issues which the General Medical Council is wrestling with at the moment and I think they are the body to define what is adequate and appropriate indemnity. Whatever else, this Directive is not going to be able to answer everything. It cannot. It can only, at a high level, give an indication of what is required and until you actually have harmonisation of the law in every different country it will be impossible to have equal redress for compensation.

Q141 Lord Wade of Chorlton: What I would like to get your view on is whether the market place is likely to try to solve the problem? In other words, if you have a specialist centre that wants to attract people they are going to have to provide all these insurance services in order to get the people. So if the Directive is passed is the market place going to find solutions to these sorts of problems?

Mr Mason: I think it will. There will be different solutions in each country because of the different legal systems.

Dr Tomkins: Certainly there are different legal systems in different countries and there will be different policies of insurance in different countries to accommodate that, however the point is that patients need to rely upon compensation if they are harmed by negligence but they are not making and are not in an informed position to make a decision about the type of indemnity that is available to the practitioner treating them. They may be referred to the tertiary referral centre but they are not in a position to decide for themselves what the indemnity arrangements will be. Insured indemnity is already a requirement in many EU states and regulated insurance is recognised across the EU and it has been established through, for example, the Non-Life Directive that there should be harmonisation of the laws, regulations and administrative provisions relating to insurance not to the delivery of healthcare.

Chairman: So really what we are saying is that we do not think the market place in the first instance will actually be able to influence and therefore we have to have proper procedures and clarity in place. I think the point you were making—with reference the Watts case for example—is that we have to move forward otherwise we will have the lawyers in the European courts making the decisions for us. We are immensely grateful to you for helping us with this which, as you can see, is complex for you and it is even more complex for we who have to deal with the issues around the whole of the Directive. Do let us know if there is anything else you want to tell us. We may well come back if we find there is an issue that we still need to clarify, but meanwhile thank you very much indeed for spending the time with us.
Supplementary memorandum by the Medical Defence Union

Thank you for your letter of 12 November 2008 enclosing a verbatim transcript of the oral evidence session to the Select Committee on the European Union: Inquiry into the European Commission’s Proposed Directive on the Application of Patients’ Rights in Cross Border Healthcare. I attach a corrected transcription with the corrections in track changes, along with brief footnotes in relation to my evidence which I hope will assist the Committee.

In relation to the MPS’s evidence, I have included some track changes dealing only with mis-spellings or typographical errors.

At question Q124, Lord Kirkwood of Kirkhope raised a query in respect of our written evidence where we cited the example of an Australian discretionary indemnifier that went into provisional liquidation, following which the government responded by passing legislation so that discretionary indemnity is now unlawful in Australia. I enclose a copy of the judgement of Austin J dated 10 November 2003 dealing with the termination of the appointment of the provisional liquidator and granting leave to discontinue winding up proceedings.

The judgement helpfully goes into the background to the provisional liquidation. The Committee may find paragraphs 48–54 of the judgement helpful. Here, Mr Lombe, the provisional liquidator, identifies the three major factors contributing to the failure of the United Medical Protection group.

The medical indemnity crisis in Australia in or about 2002–03 resulted in the introduction of legislation to regulate medical indemnity in Australia resulting in:

1. Medical defence organisations being prohibited from offering discretionary assistance on and from 1 July 2003.

2. A mandatory requirement that medical indemnity can only be offered by way of a contract of insurance by an insurer authorised under the Insurance Act, and

3. The transition of standards of prudential regulation which applied to general insurers to capture medical indemnity insurers, in particular solvency and capital requirements.

I do hope this further information is of assistance to the Committee.

17 November 2008
Memorandum by the Patient Liaison Group Royal College of Surgeons England

What do you see as the general advantages and disadvantages of patients having the right to obtain healthcare in Member States other than that where they reside? In what circumstances might patients seek to exercise any such rights?

ADVANTAGES

1. Patients may be able to get equally good treatment sooner than they would at home. This would be especially helpful for Mainland Europeans who live near borders or for those in small states, which may lack expertise/facilities, or for those with rare diseases.

2. It will only be an advantage if patients are given enough information on which to base their decision to seek treatment from another state. Some people from lower socio-economic groups may need help in making this decision.

DISADVANTAGES

1. The problems are related to language, culture, translation, continuity of care, aftercare, etc. or harm as a result of medical treatment and compensation (10% of cases report says). Psychological treatments, social care, nursing, family support would not be included. No good for the elderly who do not want to travel or those who cannot afford to travel. Dental care might be a prime target but eg in the UK NHS dental care is already stretched.

2. Patients may want to do this if there are unmet healthcare needs at home due to long waiting lists, lack of facilities for rare diseases in small countries, especially if they live near land borders and share languages—North and South Ireland would seem to be prime areas for this collaboration. It is also needed for emergencies for tourists and pensioners wintering in the sun.

3. May provide disincentives for the home State to develop procedures that they know are provided abroad and reduce research and development in their own workforce.

4. Possible inequalities of access for those who for whatever reason are unable to go to other parts of Europe to seek treatment options.

5. Could lead by default to European pockets of medical specialisation thereby reducing the training opportunities for medical students in states where the service was no longer provided, or only provided on a small scale.

6. Manpower planning is not always done efficiently in the UK, with important consequences for patient care and medical training, and may be further complicated by those deciding on workforce numbers having to assess how many patients are likely to look for treatment abroad as well as predicting demand at home.

7. Hospital acquired infection rates, which are of great concern to patients, may well be increased as a result of greater traffic in patients. Who sets the standards for coping with this?

8. It may lead to heavy demand for health services in a few countries, which could lead to delays in treatment for their own local population.
What problems do you think have arisen as a result of the present uncertainty in respect of EU citizens’ rights to obtain such cross-border healthcare and to have the costs of this reimbursed by the Member State where they reside?

1. There is no good data on what is being done and what the unmet needs are and how development of cross-border healthcare will affect healthcare financial planning because of lack of clarity. Also people do not know how to go about it. At present GPs do not present people with the option of going abroad.

What need do you see for EU level action in this field and, if you do see such a need, what objectives should such action have?

1. There has to be EU level action to ensure fairness between Member States so that any one of them is not overwhelmed (with consequent increase in waiting times for locals) with health tourists and/or queue jumpers since tax payers pay for it or in some countries patients pay a contribution. The Directive does seem to have considered the potential risks.

2. Who sets the standards for safety and quality of care?

3. Who sets the standards for medical training and the training of all health professionals, given the increasing blurring of boundaries between them, to ensure the highest quality of patient care and safety?

4. Who provides overall Quality Assurance for the process and outcomes of the system of care provided in Europe?

What is your view of the extent to which the Commission’s proposed directive will meet the objectives, if any, that you judge action at Community level should have?

1. We are not experts in EU law—but it does look as if it is all thoroughly and fairly thought out to avoid disadvantaging any one Member State.

What conditions, if any, do you feel that Member States should be allowed to impose on citizens’ rights to seek healthcare in another EU country—and to what extent do you think the draft directive satisfactorily makes provision for these conditions?

1. It should only be available for agreed medical treatment needs and the costs should be the same as they would be at home. It seems to provide for this. There are differences in the levels of care in different countries. There should eventually be standardisation in availability of certain treatments eg cancer drugs.

What limits, if any, do you think there should be to the level of costs which Member States should be obliged to reimburse to citizens who obtain cross-border healthcare—and to what extent do you think the draft directive satisfactorily makes provision for these conditions?

1. The costs should be limited to what it would have cost at home. The report says in 2006 it cost the UK £641 million so this is a substantial cost already. There appears to be satisfactory provision in the Directive.

What is your view of the likely practical impact of the proposals and of how they would affect day-to-day healthcare provision in the UK? For example, could language difficulties present an obstacle?—Who should be responsible for after care (out-patient and in-patient)?

1. Yes, for UK patients going to Mainland Europe, language is likely to be an issue because few speak EU languages fluently. It is agreed by many in the UK that good communication between medical staff and patients is a critical aspect of healthcare. This also links to EU staff practising in the UK. NHS Trusts in the UK should set minimum English language standards for all healthcare workers practising in the UK. Aftercare is another problem. Is the NHS going to have to pick up the pieces if things go wrong?

2. How do you ensure good handover back to primary care or other parts of the NHS, once a patient has received care elsewhere in Europe?

3. If revision work is needed, who does it and who pays for it? This could become a burden on the home country if it has to pick up all revisions.

4. Who follows up treatment given elsewhere in Europe when the patient gets home and how is this coordinated?
5. Who makes sure that vital patient notes and data follow the patient and are not lost or misinterpreted?
6. Who deals with any subsequent claims should that care be unsatisfactory?
7. What implications would it have for the establishment of protocols for procedures across different countries?

What is your view of the need to limit the medical conditions for which treatment could be sought in this manner?
1. It should only be for approved medical treatment that is not provided quickly or well enough at home.

How important do you feel it is to ensure that opportunities to benefit from rights to cross-border healthcare are, in practice, made equally available to all citizens and are not confined to just the wealthy or well-educated who may have the knowledge and ability to take advantage of their rights?
1. Not everybody is able or willing to travel abroad. The actual travelling may cause problems for sick people. Through a national contact point everyone who wants to find out more should be able to do so.

How do you think the aim of such equality of access should be achieved and to what extent do you feel that the draft directive is satisfactory in this respect? To what extent, for example, are the provisions on the availability of information sufficiently robust?
1. Information needs to be given to doctors and patients. Directive is clear enough. Awareness could be increased by running a national advertising campaign (like “choose and book”).

What are your views on the provisions set out in the draft directive for cooperation between Member States, including: the mutual recognition of prescriptions; the establishment of European reference networks of healthcare providers; e-health; and the management of new health technologies?
1. All of these ideas for cooperation and technical developments are useful and appropriate for the future. It could be useful to standardise healthcare across Europe by bringing all countries up to the highest level of expertise and good practice.
2. There needs to be very careful consideration of common standards, especially important for e-health, and the possible use of remote diagnosis etc. Patients must be made aware of these issues.

September 2008
The Patient Liaison Group (PLG) of the Royal College of Surgeons of England is an independent body, which reports regularly to the College’s Council. Comprising a majority of lay members (including its Chair), it provides a patient, carer, and public perspective across core College business. This submission represents the considered views of the PLG itself, and not necessarily those of the wider College or of its members.

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 really 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—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 one particular country, the resources will follow that; and that resource 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.

**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.
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.

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 by the Royal Pharmaceutical Society of Great Britain

The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation.

The primary objectives of the RPSGB are to lead, regulate, develop and represent the profession of pharmacy.

The RPSGB leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession’s policies and views to a range of external stakeholders in a number of different forums.

Following the publication in 2007 of the Government White Paper Trust, Assurance and Safety—The Regulation of Health Professionals in the 21st Century, the Society is working towards the demerger of its regulatory and professional roles. This will see the establishment of a new General Pharmaceutical Council and a new professional body for pharmacy in 2010.

We are pleased to respond to this Inquiry and would be happy to expand on any of the points made here, either in supplementary submission or oral evidence to the Committee.

1. What do you see as the general advantages and disadvantages of patients having the right to obtain healthcare in Member States other than that where they reside? In what circumstances might patients seek to exercise any such right?

1.1 General advantages

Although the European Court of Justice (ECJ) has made a number of judgements, supporting the rights of patients to obtain healthcare in other Member Countries, with re-imbursement up to the amount that they would have been entitled had they received their treatment at home, there is still much uncertainty within the EU about the application of these judgements.

1.2 The overall aim is therefore very desirable—namely to ensure that there is a clear framework for cross-border healthcare within the EU.

1.3 Patients themselves may wish to receive treatment in another Member State:

— to receive faster treatment than they would otherwise obtain in their home State;
— because they live in border regions where the hospital nearest to where they live is in another Member State;
— because they believe that the treatment they will receive in another Member State will be better than they can receive in their home State;
— to receive multi-disciplinary treatment not available in the home State (as in the EJC case of Mrs Smits); and
— because although the healthcare service they wish to access can be provided at home there are insufficient healthcare practitioners providing that service in their home Member State (eg NHS dental services).
1.4 General disadvantages

Proposal could lead to confusion and uncertainty

The proposal is in addition to what already exists under a cooperation agreement between all of the EU’s social security systems provided by Regulation 1408/71.

This Regulation includes:

- the European Health Insurance Card which covers citizens facing a health problem while studying or travelling in a Member State other than their home country and enables them to obtain medical treatment and be reimbursed for this; and

- persons who cannot get the healthcare they are entitled to in their own country within a reasonable time can be authorised to go abroad and the costs of their treatment abroad will be covered.

1.5 The existing Regulation reimburses the full cost of treatment, whereas if patients elect to go for treatment to another Member State under this proposed Directive the level of reimbursement is capped to the cost of the treatment which the patient would have been entitled to had the treatment been provided in their Member State of affiliation. Under the proposed Directive patients bear the financial risk of any additional costs arising.

1.6 What falls within the definition of “undue delay” will continue to be the subject of legal argument and lead to uncertainty. This Directive does not address this and arguably it will be the affluent patient who can afford the risk of paying additional costs who will take advantage of the Directive provisions.

1.7 Also unclear whether prior authorisation for hospital care (as defined) can be imposed from the outset or only if there is evidence that the provisions of the Directive are having a destabilising effect on healthcare provision in the home Member State.

2. What problems do you think have arisen as a result of the present uncertainty in respect of EU citizens’ rights to obtain such cross-border healthcare and to have the costs of this reimbursed by the Member State where they reside?

2.1 The problems for the UK have been minimal to date. Compared to the total number of NHS patients, few have sought treatment in other Member States and Health Authorities have reduced even these numbers by, at times, bringing their treatment forward.

2.2 The costs incurred have not proved a substantial factor and are unlikely to become so, given the protective measure of prior authorisation in certain circumstances.

3. What need do you see for EU level action in this field and, if you do see such a need, what objectives should such action have?

3.1 The stated aim of the proposed Directive is to:

“establish a general framework for the provision of safe, high-quality and efficient cross-border healthcare in the European Union and to ensure free movement of health services and a high level of health protection”

The framework is needed and deserves to be supported in principal.

3.2 Health Professionals

The Royal Pharmaceutical Society of Great Britain has a particular interest in the position of health professionals.

3.3 When patients cross borders to receive treatment or when health professionals cross borders to provide services to “ensure a high level of health protection” there has to be a high degree of cooperation and exchange of information concerning not only the patient’s medical history but also information concerning the health professional’s fitness to practise and assurance of current professional competence and language competence.

3.4 The proposal should strengthen the ability of healthcare regulators to require their counterparts in other Member States to disclose fitness to practise information on practitioners who wish to move to another Member State to practise. Healthcare Professionals Crossing Borders (HPCB) which is an informal partnership of professional regulators from within Europe has worked collaboratively to encourage information exchange but has found that although Directive 2005/36/EC requires collaboration on information exchange some regulators are prevented from doing so because of rigid national interpretations of data protection legislation. In its response to the European Commission’s consultation regarding Community action on health services in January 2007, the Alliance of UK Healthcare Regulators on Europe (AURE)
called upon the European Commission to explore the establishment of a legal duty upon regulators to share information with each other.

3.5 The proposed Directive should make it a legal requirement for:
   — the home Competent authority to alert the host Member State Competent Authority if a practitioner has been subject to fitness to practise proceedings in his home Member State that could impact on his right to practise there; and
   — the home Competent authority to disclose fitness to practise information on practitioners who wish to move to another Member State to practise.

This would ensure that patient safety is central to the free movement of health professionals in Europe.

3.6 The proposal should also enable regulators to check the language competency of healthcare practitioners who intend to provide healthcare services on their territory.

3.7 Additionally the proposal should also include provisions relating to revalidation to provide assurance of current practitioner performance competence when practitioners seek to practise in other member states.

3.8 Under Directive 2005/36/EC, the right to provide health services on a temporary and occasional nature is based on the practitioner’s continued right to practise in their home Member State. This is of particular concern as the approaches to a professional’s fitness to practise vary significantly from country to country. Some Member State have strong distinctions between professional and private conduct and would not consider imprisonment for a crime unrelated to their professional practice as impinging on a practitioner’s right to practise.

3.9 In the case of temporary service provision in particular the standards applied are therefore not the standards of the Member State of treatment but the Member State where the practitioner comes from. The Directive should amend this to provide that the standards to be applied in all circumstances are those of the Member State of treatment.

4. What is your view of the extent to which the Commission’s proposed directive will meet the objectives, if any, that you judge action at Community level should have?

4.1 The proposed Directive sets laudable aims but a number of important issues remain to be clarified as set out above.

4.2 Furthermore in relation to the cross-border recognition of prescriptions, pharmacists, prior to dispensing, should be able to verify the status of the prescriber and check whether the individual is indeed authorised to prescribe in his home Member State.

4.3 The proposed Directive should make it a legal requirement for:
   — Member States to have real-time web-based publicly searchable lists of registered professionals.

5. What conditions, if any, do you feel that Member States should be allowed to impose on citizens’ rights to seek healthcare in another EU country—and to what extent do you think the draft directive satisfactorily makes provision for these conditions?

5.1 The draft directive rightly permits a prior authorisation scheme to protect against any serious undermining of the home State healthcare arrangements.

6. What limits, if any, do you think there should be to the level of costs which Member States should be obliged to reimburse to citizens who obtain cross-border healthcare—and to what extent do you think the draft directive satisfactorily makes provision for these conditions?

6.1 We believe it right that Member States should reimburse patients up to the amount that they would have been entitled had they received their treatment at home.

6.2 Also to some extent depends on how—“undue delay” and provisions of Article 22(1)(c) and Article 22(2) of Regulation 1408/71 are interpreted.

6.3 A relevant factor to possibly consider here is Government policy relating to top-up payments. If patients are permitted to top up their healthcare by buying medicines that have been ruled too expensive to be made available on the NHS this would permit patients to pay for these medicines irrespective of whether they had been prescribed in the UK or another Member State and continue to receive NHS/reimbursable healthcare.
7. What is your view of the likely practical impact of the proposals and of how they would affect day-to-day healthcare provision in the UK? For example, could language difficulties present an obstacle?—Who should be responsible for after care (out-patient and in-patient)?

7.1 The Directive recognises that patients need to have clear detailed information about:

— The system of healthcare in other Member State to enable them to make an informed decision about where they want to receive treatment. It is acknowledged that this should include “transparency about applicable standards for patients and professionals”.

— Who is going to be responsible for the continuity of their care and what will the continued treatment plan involve.

— Mechanisms to ensure appropriate remedies and compensation for harm arising from healthcare.

7.2 However the proposals appear not to address these identified needs in a sufficiently robust manner. For example in the absence of real-time web-based publicly searchable lists of registered professionals and an assurance that those whose names appear on the register are fit to practise (preferably in accordance with character and health checks such as those required by UK regulators) patients cannot make an informed decision about where they want to receive treatment.

7.3 Additionally patients will need assurance that the healthcare practitioners will be able to communicate with them in their own language and that medical information exchanged is in the appropriate language to facilitate continuity of care.

7.4 In relation to continuity of care, communication of healthcare information from eg secondary to primary care (or vice versa) even within the UK can be delayed or be incomplete. This information exchange may be subject to potentially greater delays, errors and miscommunications when information is transferred between professionals/organisations in different Member States. Language may be a barrier, names of medicines used may be different.

7.5 In relation to appropriate remedies and compensation, it is difficult enough to prove causation and obtain redress for harm arising within a single jurisdiction. It would be even more complex when this is across jurisdictions. The proposed Directive states that for the purposes of clarity the “rules applicable to the actual provision of healthcare is governed by the rules of the Member State of treatment” (p 18). If something goes wrong, patients would be guaranteed redress and compensation, according to the rules of the country where treatment was provided. In cross-border prescriptions if something goes wrong and the patient suffers harm—what is the Member State of treatment?

Is the patient to get redress and compensation, according to the rules of the country where the prescription was written or according to the Member State where the prescription was dispensed?

7.6 Doctors/pharmacists share responsibility. There are at least two High Court decisions where liability for harm caused has been assigned, proportionately to the extent of their individual contributory negligence, to both the pharmacist and the prescriber.

7.7 In circumstances where the patient does not cross borders to receive care but instead the healthcare practitioner moves to provide care on a temporary and occasional basis under Directive 2005/36/EC, the patient might assume that the standards applied to the practitioner’s right to practise are likewise governed by the Member State where the treatment is received. This is not the case however—a temporary healthcare provider’s right to practise are based on his subsisting right to practise in his home Member State of establishment which may have different standards of fitness to practise than the host Member State regulator.

8. What is your view of the need to limit the medical conditions for which treatment could be sought in this manner?

8.1 The Royal Pharmaceutical Society believes that the presumption should be in favour of all medical conditions unless there are good reasons to the contrary.

9. How important do you feel it is to ensure that opportunities to benefit from rights to cross-border healthcare are, in practice, made equally available to all citizens and are not confined to just the wealthy or well-educated who may have the knowledge and ability to take advantage of their rights?

9.1 The Directive does not propose that cross-border healthcare should favour any group and this is a view that we fully endorse.
10. **How do you think the aim of such equality of access should be achieved and to what extent do you feel that the draft directive is satisfactory in this respect? To what extent, for example, are the provisions on the availability of information sufficiently robust?**

See responses to questions 1 and 7.

11. **What are your views on the provisions set out in the draft directive for cooperation between Member States, including: the mutual recognition of prescriptions; the establishment of European reference networks of healthcare providers; e-health; and the management of new health technologies?**

11.1 We believe that there is:

— a need to ensure that community prescriptions comply with UK legal requirements;

— verification is required on whether the prescriber is legally authorised to prescribe. As explained above, this would need web-based searchable registers of prescribers who are fit to practise in their Member State; and

— a need for prescriptions written by UK-registered nurses/pharmacist prescribers be recognised in other Member States, as non-recognition could hinder continuity of treatment for the patient.

11.2 We recommend that the proposed Directive should make it a legal requirement for:

— The home Competent Authority to alert the host Member State Competent Authority if a practitioner has been subject to fitness to practise proceedings in his home Member State that could impact on his right to practise there.

— The home Competent Authority to disclose fitness to practise information on practitioners who wish to move to another Member State to practise and should also legally permit the host Member State to check the language competency of practitioners who wish to provide healthcare services on their territory.

11.3 Additionally the proposal should also include provisions relating to revalidation to provide assurance of current practitioner performance competence when practitioners seek to practise in other member states.

12. **Other matters**

12.1 The proposed Directive contains the following statements which appear to be contradictory:

12.2 At page 9 it is stated that:

> “the proposal does not change the right of Member State to define the healthcare benefits that they choose to provide to their citizens. If a Member State does not include a particular treatment as part of the entitlement of their citizens at home, this mechanism does not create any new entitlement for patients to have such treatment abroad and be reimbursed”.

12.3 However at page 28 preamble 27 states:

> “This Directive provides also for the right for a patient to receive any medicinal product authorised for marketing in the Member State where healthcare is provided, even if the medicinal product is not authorised for marketing in the Member State of affiliation, as it is an indispensable part of obtaining effective treatment in another Member State.”

12.4 Would treatment with the medicinal product which is not licensed in the Member State of affiliation be reimbursed under the proposed Directive?

Also, does this assist with ensuring continuity of care in circumstances where treatment may need to continue with an “unlicensed medicinal product” on the patient’s return to his Member State of affiliation?

12.5 On a separate issue—in the case of e-health/e-prescriptions/telemedicine etc where neither the patient nor the healthcare provider move but the service “moves”—is this covered by the definition of cross-border healthcare in Article 4 of the proposed Directive?

26 September 2008
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,
pharmacy technicians to have a code of ethics that requires pharmacists and et cetera. Once on our register, they are bound by our world and we do, including Australia, New Zealand, cannot demand evidence of English language with us. We have to register EEA nationals and competence from EEA nationals wishing to register unable to require evidence of English language nationals wishing to come over. Currently we are to language is English language competence for EEA the areas where we have particular concern relating certainly many di

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?
Among our members we provide a long list of ways for Swiss, Polish or Bulgarian medical registers. We have mentioned before one of the problems is in being confident that it was written by a genuine doctor. As I have mentioned before, one of the problems is in applying your professional judgment to it, in the same way as you would to any other prescription. Pharmacists would also need to be able to dispense on an EEA prescription a drug that is not marketed in this country. We agree that if a pharmacist is unclear or concerned about, say, Germany but not in this country. We would not be able to dispense 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.

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 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.

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.

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 we are 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.

Supplementary memorandum by the Patient Liaison Group Royal College of Surgeons England

Q1

A. On the basis of your practical experience as a patient group, what is your view of the need for EU level action in this area?

B. What do you consider should be the key objectives of this proposal?

Q1. B. KEY OBJECTIVES:

ISSUE OF PATIENT CHOICE IS NOT CLEARLY DEALT WITH IN THE DIRECTIVE

— HOW IS THE TREATMENT CHOICE MADE IN THE FIRST PLACE?
Assumption in the Directive seems to be that the movement of patients will automatically lead to improvement in services throughout the EU.
Assumes patients will inevitably choose best treatment options.
However, patient choice is often subjective—decisions may be made on length of wait alone for example.
Who guides the patient in this choice?
Only just started to look at developing clinical outcome information in UK as basis for patient choice—far more complex across the EU.

EMPHASIS FOR STANDARDS OF PATIENT CARE ETC IS ON GUIDANCE IN THE DIRECTIVE

— METHODS OF IMPLEMENTATION NOT SPELT OUT

Q2

A. In your written evidence you identify the importance of providing information to patients to ensure they make an informed decision about treatment. What do you think such information should consist of?

Q2. A. WHAT INFORMATION?

— GENERAL INFORMATION
What it means
How to do it
Who to approach
Where to get advice about process

— LOGISTICS AND OTHER DETAILS
How to get there
Costs of care/What included in reimbursement
Transport costs and whether these include travel for an accompanying relative
Documents required
Language used in the unit.
— CLINICAL INFORMATION
   Enough information to be able to make an informed choice
   Clinical outcome data
   What form the treatment takes
   Who will perform the procedure?
   Waiting times

— LESS TANGIBLE ASPECTS OF CARE
   Likely patient experience
   Levels of caring and general support provided

— HOW TO GET BACK ON THE PATHWAY OF CARE BACK HOME
   How coordinated
   Who responsible

— HOW TO MAKE A CLAIM IF IT GOES WRONG
   Procedure to follow

November 2008
CROSSBORDER HEALTHCARE : EVIDENCE

THURSDAY 20 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 by the General Medical Council

1. The General Medical Council (GMC) is the independent regulator for doctors in the UK. Our purpose is to protect, promote and maintain the health and safety of the public by ensuring proper standards in the practice of medicine.

2. There are currently approximately 250,000 doctors on the UK Medical Register, some 22,000 (9.0%) of which qualified in other parts of the European Economic Area.

3. The law gives the GMC four main functions:
   a. keeping up-to-date UK registers of qualified doctors;
   b. fostering good medical practice in the UK;
   c. promoting high standards of medical education in the UK; and
   d. dealing firmly and fairly with doctors practising in the UK whose fitness to practise is in doubt.

4. Our approach to medical regulation stresses the importance of professionalism in raising healthcare standards and subsequently reducing risks to patients. We believe that the development of this approach to medical regulation across Europe could make a significant contribution to safe and high quality healthcare in the context of patient rights in cross-border healthcare.

5. We set out below our view of the draft Directive based on several of the questions set out in the Call for Evidence.

ASSURING SAFE AND HIGH QUALITY HEALTHCARE

6. The Directive on the application of patients’ rights in cross border healthcare must provide for the patients’ right to effective medical regulation. This should encompass: patient-safety-centred medical regulation across Europe; transparent national and/or regional regulatory processes and information for patients, the public, professionals and regulators; efficient and proactive professional regulatory collaboration; and high safety and quality standards set at national and/or regional level.

7. The standards, role and practice of medical practitioners cannot be decoupled from quality and safety concerns across all healthcare provision. Nor can assurances, for patients and the public, about the fitness to practise of doctors based in other European Member States, be distinguished from those required for doctors who choose to exercise their rights of free movement. They are in principle the same doctors.

8. All patients in Europe must have the assurance that the doctors that treat them—whether at home or abroad—are practising in accordance with robust professional and ethical standards. These include relating to quality, professionalism, confidentiality, continuity of care, and the communication of patient records.

9. It is also important that professional and ethical standards are developed at the national or regional level in order to take account of cultural and practical considerations.

10. Our professional guidance, Good Medical Practice—which has been developed in the context of a wide range of UK stakeholder groups, is increasingly embedded in health service delivery in the UK. We do not believe the setting of professional standards at European level is of added value. It could result in greater risk to patients through the application of lowest common denominator standards, to the detriment of safe and high quality healthcare.

11. It is inevitable that as a doctor moves through his/her career their practice changes. Sometimes they may have difficulty in continuing practising in accordance with the standards that are expected of them. There should be mechanisms in all Member States to enable the regular evaluation of a doctor’s practice in order to assure patients that they continue to be competent to practise.
12. The GMC is working on plans to change the way doctors in the UK are regulated to practise medicine, in the form of licensing and revalidation. This will be the single biggest change to medical regulation since the establishment of the GMC 150 years ago.

13. The first change will come in late 2009 when the GMC will introduce licences to practise. All doctors in the UK will be required by law to hold a licence if they wish to exercise the legal privileges currently reserved for registered medical practitioners (such as prescribing medication and signing death certificates). All doctors holding a licence to practise will need to participate in revalidation. This means they will need to collect evidence about their practice to support their future revalidation, participate in annual appraisal in the workplace and in an independent process for obtaining feedback from patients (where applicable) and colleagues will need to collect of information about their practice. This will include, for example, information about appraisal, continuing professional development, audit, and patient and colleague feedback.

14. The purpose of this new approach is to give patients a regular assurance that licensed doctors are up to date and fit to practise. Revalidation is not only designed to find doctors whose fitness to practise is impaired. It is designed to promote excellence in clinical practice and, through supporting the professional development of doctors, enhance patient safety.

15. Medical Revalidation in the UK could become a model of good practice for medical regulators across the European Union. We believe all regulatory jurisdictions should develop similar approaches to provide assurance to patients, the public and other regulators of doctors’ continued competence to practise.

THE PATIENT’S RIGHT TO EFFECTIVE MEDICAL REGULATION

16. The focus of the draft Directive is the patient’s right to access treatment in another member state and the right to safe and high quality healthcare for all patients. Alongside this must sit a right for patients to effective, fair and robust medical regulation—whether the patient is treated at home or abroad. Regulatory responsibility must rest with the “member state of treatment”.

17. The nature and approach to medical regulation in Europe differs from jurisdiction to jurisdiction. A patient’s healthcare experience in another European member state and the process for regulatory redress if things go wrong, may not be the same as at home. There must be greater regulatory transparency across Europe for patients, the public, professionals and other regulators.

18. In the UK, we have a freely accessible web-based real-time list of registered medical practitioners—patients can check anytime that the doctor treating them is registered and has no disciplinary action against them. We make our standards and guidance freely available to the public via our website and on request, and we set out on our website the mechanism for making complaints about a doctor and notifications of disciplinary hearings.

19. We have also recently launched Patients’ help—an interactive site which helps patients in the UK to understand which organisation to complain to if they have concerns about their doctor. It enables users to listen to a range of case studies, view an “at a glance” chart on the life cycle of a complaint and look up local contact details on an interactive map.

20. While promoting transparency and access to information, the Directive must not impose any disproportionate administrative burdens on medical regulators, particularly if in reality there will only be small numbers of patients exercising their right of free movement to access healthcare in another European Member State. Patients must be able to access information by the most authoritative means and we believe this should be from the prospective member state of treatment.

INFORMATION EXCHANGE BETWEEN REGULATORS

21. For some time we have called on the European Commission to introduce a legal duty on all medical regulators to share registration and fitness to practise information proactively with other regulators in Europe. In all circumstances this is important to ensure that doctors, exercising their rights of free movement, are only granted registration when they are known to be fit and safe to practice. It is also important when doctors are simultaneously registered in more than one European regulatory jurisdiction. If information is not shared efficiently and effectively a doctor could, unwittingly for the regulator, be erased or suspended in one jurisdiction while continuing to practise and potentially harm in another.

22. The European Parliament has already agreed with us on the need to establish a legal duty on information exchange. The Parliament called for this in both the “resolution of 15 March 2007 on Community action on the provision of cross-border healthcare” and in the “resolution of 23 May 2007 on the impact and
consequences of the exclusion of health services from the Directive on services in the internal market” (2006/2275(INI)).

23. The Directive must introduce a legal duty on national and regional regulatory authorities to reactively and proactively exchange registration and disciplinary information about the doctors their register.

PROMOTING THE PRINCIPLES OF GOOD MEDICAL REGULATION

24. Medical regulation in Europe must appropriately comply with the principles of good regulation. In this regard regulation should be targeted, proportionate, accountable, consistent and transparent. It should also take place at the level most able to maintain patient safety and to deal firmly and fairly with doctors whose practice falls short of expected standards.

25. There should be no ambiguity as to where regulatory responsibility rests in any case of cross border healthcare. In particularly complex situations, such as e-health, where neither the patient or professional physically moves, there must be clarity as to who holds regulatory responsibility.

26. The GMC cannot hold regulatory responsibility for doctors who are not on the UK Medical Register nor are physically practising in the UK. It must be the responsibility of contracting bodies to assure themselves that any e-health contractors are appropriately registered and qualified in the country from which they are practising. Furthermore there should be no ambiguity as to the role of the European Commission in relation to medical regulation. The role of the “Implementing Committee”, proposed in the draft Directive, should be defined and limited in law to avoid future disproportionate, unanticipated and inappropriate spill-over into the national regulatory role.

CONCLUSION

27. The GMC believes the fundamental purpose of medical regulation is to ensure safety and quality of care for patients. Our approach to regulation is based on the fostering of professionalism. We believe that greater professionalism will drive up clinical standards and contribute to continuous improvement in patient safety. This makes effective medical regulation a vital component in achieving safe and high quality healthcare for all across Europe.

October 2008

Memorandum by the Nursing & Midwifery Council (NMC)

The Nursing and Midwifery Council (NMC) has received the call for evidence published by the House of Lords, Select Committee on the European Union, Sub-Committee G (Social Policy & Consumer Affairs).

We wish to respond to the following particular questions:

What do you see as the general advantages and disadvantages of patients having the right to obtain healthcare in Member States other than that where they reside? In what circumstances might patients seek to exercise any such right?

1. We understand that European legislation on patient mobility will provide better choice for patients to seek treatment cross-border according to their needs. However, we, foresee problem areas regarding the patient’s right to information when health services are provided cross-border.

2. The issues the NMC foresees as a result of the draft directive could be summarised as:
   — patients not being familiar with the scope of practice of the health professional treating them and assuming that this is the same as in their country of residence;
   — patients not having enough information as to who they should address for a complaint against a health professional or not even knowing they have the right to complain; and
   — patients always assuming that the professional providing the service is fit for practice under the same rules as in her/his Member State of origin.

3. For the above reasons, we believe that information to patients about the role of the health professional in the country where they receive the service is important. Of equal importance is the role of regulators in ensuring patient safety and public protection. Patients receiving services in the UK should be informed about the role of regulators in receiving and managing complaints, setting standards for education and practice and informing patients about health professionals’ role in the healthcare system.
What need do you see for EU level action in this field and, if you do see such a need, what objectives should such action have?

4. There is a need to ensure quality of care and patient safety when services are provided cross-border. There is also a need for patients to understand where/how they can complain when something goes wrong.

5. EU level action in this field could involve:
   — Member States exchanging proactively information on professional misconduct of health professionals providing services cross-border. This could be followed through the means of e-health (either through on-line software of information exchange or the use of standardised European professional cards). We understand data protection acts in several European countries could prevent this from happening but patient safety should not be negotiated against the protection of a professional.
   — In order for the patient to know where/how to complain when something goes wrong, concrete and clear information as to the role of the different competent authorities should be available via a national contact point. Health regulators in the UK would be in the position to be part of this information sharing.
   — Member States to invite regulators to proactively exchange information on the scope of practice of professionals in the different countries. This would involve regulators providing information as to the services a registered health professional should be expected to provide to a patient according to set standards in the country where the professional is registered.

What is your view of the likely practical impact of the proposals and of how they would affect day-to-day healthcare provision in the UK? For example, could language difficulties present an obstacle? Who should be responsible for after care (out-patient and in-patient)?

6. One of the areas of concern is the directive’s provision on patients’ right to continuity of care cross-border. This involves the patient receiving a service cross-border and then continuing receiving care in her/his country of residence. Such practice will involve a number of healthcare professionals in at least two different Member States. This raises concerns with regard to liability. If something went wrong and the patient wished to complain and seek compensation, it would be impossible to reply to such a need unless exchange of data took place cross-border. Because of data protection acts in several European countries, we believe that this is an area of concern.

7. Another area of concern regards the arrangements to be put in place for dealing with legal disputes. We agree that these should be followed according to the legislation of the Member State of treatment, not the legislation of the patient’s place of residence. When it comes to complaints or legal action against a professional, this should be made in the Member State where that professional provided the service, which is the Member State where she/he is registered.

8. However, we foresee ambiguity as to what will be considered to be the Member State of treatment when it comes to cross-border prescribing: will it be the Member State of the prescriber or that of the professional who administers or dispenses the drug when these take place cross-border?

9. We also foresee confusion with those professionals who will be providing services on a temporary basis. The patient might assume that standards applied to the health professional’s right to practise are governed by the Member State of where the treatment is received. This is not the case: a temporary healthcare professional’s right to practise is based on his home Member State of establishment.

10. The language competence of healthcare professionals when providing a service cross-border and the inability for regulators to assess this under the Recognition of Professional Qualifications has always been an issue.

11. Along with other regulators, the NMC is of the view that patients should be able to receive care in a language they are familiar with. We understand, though, that when patient mobility and professional mobility happen simultaneously effective communication is further complicated.

12. For the above reason we propose:
   — For regulators to be able to ask information about the language competence of professionals seeking registration.
   — For regulators to be able to ensure that professionals communicate effectively in at least one of the official languages of the country they will be providing the service in.
What are your views on the provisions set out in the draft directive for cooperation between Member States, including: the mutual recognition of prescriptions; the establishment of European reference networks of healthcare providers; e-health; and the management of new health technologies?13. The UK is one of the few European countries where nurses and midwives may prescribe following standards defined by the NMC. This should be taken into account in any measure developing a Community prescription template and the rules that will support it. We would like to be ensured that prescriptions written by an authorised nurse or midwife prescriber in the UK will be recognised in other Member States. Non-recognition could put obstacles to the patient’s continuity of care.

14. The existing diversity within Europe with regard to medicines management and prescription rules, as well as the diversity of drug’s names, dosage and availability should be taken into account in any provisions made for the recognition of prescriptions. We understand that recognition of prescriptions will be made via electronic means and this would not involve recognition of handwritten prescriptions, which could lead to confusion. However, inability for professionals to understand a prescription available either in a different language or using different terminology and dosage measures could lead to putting patient safety at risk.

15. The NMC welcomes the use of e-health and new technologies as a means for Member States to share information and for patients to receive it. E-health would be particularly useful in the share of patient data, recognition of prescriptions, share of information on a professional’s misconduct or criminal record or even on a professional’s Continuous Professional Development activities.

Other issues not included in the inquiry specific questions

16. Applicable rules to healthcare provided in another Member State (Article 11): The NMC is seeking clarification as to what rules apply as far as the recognition of the professional qualifications is concerned. The current draft does not guarantee that all healthcare services will be provided according to the legislation of the Member State of treatment even those provided by health professionals who have been subjected to recognition of their professional qualification under the rules of Directive 2005/36/EC.

26 September 2008

Examination of Witnesses

Witnesses: Mr Finlay Scott, Chief Executive, and Ms Claire Herbert, Head of European and International Development, General Medical Council; Mrs Jill Crawford, President, Mr Graham Smith, Chief Executive Officer and Dr Katerina Kolyva, EU and International Manager, Nursing & Midwifery Council, examined.

Q191 Chairman: Welcome. Thank you very much for taking the time to come and give us your evidence. We think that this inquiry into the Cross-border Directive is extremely important. I must say that it has turned out to be rather more complex than most people had originally anticipated and grows more complex every time we hear witnesses. We will be hearing from both groups together. Some members may address their questions to a particular group, but if you have something to say at the end of one group’s evidence please indicate so that we can hear it, but we do have to get through quite a lot in a short time so precision is everything. If we get to the end and you have not said everything you want to say, we are very happy to receive supplementary evidence from you and for you to amplify any questions you think may have been raised during the discussion that we have not quite got to the end of. What I am going to do is to ask you all to give your names for the public record and then, only if you so wish, to ask each group to make a short introductory statement. Maybe I could start with the GMC and ask if you would state your names and your positions for the record.

Ms Herbert: Claire Herbert, Head of European and International Development at the GMC.
Mr Scott: I am Finlay Scott. I am the Chief Executive at the GMC.
Mrs Crawford: I am Jill Crawford and I am the President of the Nursing & Midwifery Council.
Mr Smith: Graham Smith, Chief Executive and Registrar of the Nursing & Midwifery Council.
Dr Kolyva: Katerina Kolyva, EU and International Manager at the Nursing & Midwifery Council.

Q192 Chairman: Thank you very much indeed. Do either group wish to make a short introductory statement?
Mr Scott: May I make a very short statement, my Lord Chairman. The GMC’s purpose is to protect, promote and maintain the health and safety of the public by ensuring proper standards in the practice of medicine. Our mainly recognised public face is that we take action when things have gone wrong, but arguably the main contribution we make to high standards of healthcare is through our influence upon medical education and training and through
the production of guidance for the profession in rapidly changing and demanding times. I would, if I may, just make four quick points in relation to the topic today. One, we believe it is essential that regulators across Europe should have in place measures that demonstrate to the public that their licensed or registered doctors are fully up-to-date and fit to practise. The second point is that the reality of healthcare is that it is not delivered by individuals working in isolation, it is delivered by teams normally within systems and we therefore require effective systems of system regulation of the kind provided by the Healthcare Commission or, in future, the Care Quality Commission. Third, it is very important that we have effective local systems through clinical governance that are able to act quickly and effectively if there is a suspicion that things have gone wrong. Finally, there have to be effective systems that lead to regulatory action or redress for patients if they have been harmed. Our general view is that freedom of movement can be a very good thing, but historically the interests of enabling freedom or encouraging freedom have sometimes not taken full account of the needs of patients and patient safety. Thank you.

Q193 Chairman: Thank you very much. Can I ask if the NMC want to make an introductory statement? Mrs Crawford: Thank you, if I might say a few words. The Nursing & Midwifery Council is the regulator of the 750,000 nurses and midwives in the UK. Similar to the GMC, we regulate the individuals, we are not a system regulator. Our role is entirely public protection, we are patient-safety focused, and our response today is from that perspective. The points that I would like to make echo many of the points that the GMC have made. In terms of the Directive, there does need to be a strong requirement for cooperation on a regulatory level between EU Member States and regulators, and this needs to be a legal requirement. Patients should have the right to know that any professional treating them is registered, is reputable and should be able to have access to that person’s fitness to practise record. We also support the principle which is within the Directive that responsibility for that should sit with the regulator where the treatment is given. Those are the three key points I would like to draw to your attention at this stage. Thank you.

Q194 Chairman: Thank you very much indeed. Both of you in your statements as well as your evidence raise this issue of effective regulation in relation to the Directive. As medical regulators, how well do you think that the Directive addresses the issue of medical regulation in cross-border healthcare? What do you consider to be the most important points in this regard and where do you think, and this is an important area, the regulatory responsibility should rest in cross-border treatment? I am going to start with the GMC. Mr Scott: I think the absolute starting point should be that responsibility has to be clearly defined. There is a phrase that is sometimes used, “collectively exhaustive and mutually exclusive”, which points to single lines of accountability whatever the circumstances. That single line of accountability has to hold true whether it is the patient who is mobile or the healthcare professional. As a matter of law we could not take responsibility for healthcare professionals in other countries who are not registered with us. As a matter of practice, even if we were able to consider accepting such a responsibility, it would be almost impossible to deliver. We feel strongly that the line of accountability, as Jill has said, should be built around the point of delivery of the particular service that is in question. In our case, therefore, it means two things: in general national governments should put in place legislation that controls the delivery of healthcare services such that professionals have to be registered in order to deliver a service; secondly, as is the case with us, no matter where a doctor is practising, if they are registered with us they remain accountable to us.
regulatory systems need to be explicit and transparent. Patients need to have very easy access to who is responsible and where accountability sits.

Q197 Lord Lea of Crondall: Is there not a potential anomaly of lack of reciprocity in what you are both saying here; that you would expect perhaps that a British doctor in Poland in their scheme, which is happy to register all-comers from EU countries, is fine and dandy but in this country you would be in a position of holding your own autonomy in saying you could not recognise necessarily them or country X here. In practical terms you would need to have some discussion with them about reciprocity at some stage, would you? How would you talk to them?

Mr Scott: I think there are two quite distinct circumstances. One is where the doctor in Poland, irrespective of their nationality, is registered only in Poland. In those circumstances we would not be able to contemplate taking action against them despite the fact that the complaint or source of concern emanated from a UK citizen. The second circumstance is where the doctor in Poland is also registered with the GMC in the United Kingdom. In those circumstances we would be able to take action against them, either first order action in advance of action by the Polish authority, or second order action based on the findings by the Polish regulatory authority. Just to emphasise, what we could not practically deliver is a decent regulatory response to doctors who simply were not registered with us in the first place.

Chairman: Thank you, that is very helpful in clarifying that.

Q198 Baroness Perry of Southwark: I want to ask a question about the provision of information which follows some of the issues. Both of you in your written evidence believe that the provision of information to patients is extremely important, but that is a pretty huge job when you come down to it. Who do you think should be responsible for providing that information?

Mrs Crawford: At the first level in terms of patients having information about their rights, about the ability to access care in other EU countries, clearly the Directive states there ought to be a national contact point to provide that. From a regulatory point of view, the more significant part is the information that patients are given by the professional and the need for that information to be accessible to them, the need for that patient when they access care to understand what they are being told, to be able to give informed choice. From a regulatory point of view the patient could not waive their right to giving informed choice, there is a need for that professional to be confident that they have delivered care in a way that is accessible to any individual they are treating. Talking about information in terms of patients’ rights, that needs to be a national contact point, and it would be the NMC view that we would like to input into that in terms of the scope, the practice of individuals, the regulatory system within the UK, but clearly we would not seek to be that point of contact.

Q199 Chairman: Could you just define what you mean by a “national contact point”?

Mrs Crawford: I am using the phrase from the Directive. Our response would be that it is a governmental issue to establish and decide where that national contact point sits.

Q200 Chairman: You do not have a view about it, because we have not been able to get other people to tell us?

Mrs Crawford: I think our view is that it would not be us but we would like to input into it.

Mr Scott: I quite agree with Jill that we have to be careful not to impose requirements upon UK regulators that they cannot realistically deliver. I very much agree that the primary source of information should be in the country where the service would be delivered. Incidentally, I think it needs to cover the four points that we briefly touched on in our introductory statement. What I do see is that there is an opportunity to use technology to make it very much easier for patients, their doctors and friends to access that information, for example through links from websites. So you could imagine that in each country there might be one or more common portals as a way of gaining access to information, but the primary responsibility would remain with the intended country of treatment.

Q201 Baroness Perry of Southwark: What kind of information do you think patients are entitled to? How much should they be given or have access to?

Mr Scott: Can I preface my answer to that by saying that we are fortunate in the UK in having a very well established and robust system of general practice. Our starting point would be to advise individuals not, as it were, to do this on their own but to do it in conjunction with their own UK medical adviser. It needs to cover at a minimum, in our view, the system of regulating professionals, including that very important point, is there a systematic approach to demonstrating that in our case doctors remain up-to-date and fit to practise. Secondly, is the system as a whole regulated, are hospitals and other healthcare units subject to regulation and, if so, frequency and effectiveness. Thirdly, what systems of local clinical governance exist to ensure early and effective action. Finally, because unfortunately things will go wrong,
it is the nature of healthcare that sometimes they will go wrong, how do patients gain access to redress. I think that is the minimum core set of information. Mrs Crawford: The only thing that I would like to add or strengthen is that part of the information that patients get has to be about the regulatory frameworks within different countries. UK patients are at particular risk because there is an assumption within the UK that there is system regulation, there is individual regulation of health professionals, and we know in other EU Member States that looks very, very different, so there will be an illusion of regulation across the EU which is not real. Part of that information for patients to make an informed choice has to be the kind of regulatory system that they are choosing to go into.

Chairman: To have that properly in place is going to demand co-operation between the States. Lady Young is going to pursue this co-operation question.

Q202 Baroness Young of Hornsey: On the subject of co-operation on two specific areas, first of all, and this is particularly directed at the NMC because you raise this issue around prescriptions, in the draft Directive there is provision for EU-wide recognition of prescriptions, what is your view on that? What do you consider to be the potential advantages and/or disadvantages of that provision, especially in the case of where I think you say in your written evidence that we are in quite a unique position in this country where nurses can prescribe? What are the potential disadvantages and advantages?

Mrs Crawford: You are right, there is a particular regulatory issue for us, which is that nurses and midwives can prescribe having undertaken certain training and that would not be widely recognised around the EU, so there may be issues of other Member States recognising the validity of a prescription that has been issued by a nurse or a midwife. That is a specific issue to nursing and midwifery. Part of the answer to that is their being given clear information on the different scopes of practice of nurses and midwives within the UK and other EU Member States. There are other issues which are really purely patient safety issues. They may not sit within the regulatory framework in a very clear sense, but they are significant. The idea of EU-wide prescribing in practice is very difficult to implement. The language issues make it significant and there are different alphabets within the EU which makes it very difficult. In terms of the cross-border collaboration between the prescriber and the dispenser there are some fundamental communication issues which the NMC is not convinced will be picked up purely by having an EU-wide electronic template for prescribing.

Q203 Baroness Young of Hornsey: Do you think that those barriers can be overcome or is it more or less impossible and we will have to settle for something else?

Mrs Crawford: There would be clear benefit to overcoming those barriers because the alternative is that when somebody has accessed treatment in another EU Member State and returns to their home Member State they are simply going to have to go through the whole prescribing process again, and potentially there will be patient safety issues in terms of the accessibility of those records. I would seek to resolve them. The principle is a good one, but there needs to be much more work done and there need to be very clear guidelines and standards for the implementation of it.

Q204 Baroness Young of Hornsey: Does that situation arise now from different circumstances, for example if somebody is taken ill on holiday or something? I would imagine that sort of situation might currently occur.

Mrs Crawford: I do not know firsthand on this, so I will not make it up.

Q205 Baroness Young of Hornsey: No, that is fine. Did the GMC want to say anything?

Mr Scott: There are two different circumstances which should be touched upon. One is where the patient returns to the UK with a prescription written by a doctor or another healthcare professional in another country and the reality is that today across Europe as a whole pharmacists would not have uniformly easy access to the equivalency of our list of registered medical practitioners. Although in theory that can be addressed, the history of the development of trans-EU systems is not very encouraging. There is also a second circumstance which I was discussing with a UK doctor yesterday. One of her patients had returned from IVF treatment in another country, not with a prescription but with an extended request for a prescription which the patient invited the doctor to meet. In other words, it was not a direct message from one healthcare professional to another, it was an indirect message, and the clear intent was to encourage a UK doctor to provide a prescription not in correspondence with her own diagnosis of what was required but a third party's diagnosis. Again, there is a second side to this to which we have to be very alert.

Q206 Lord Trefgarne: Would you not agree that to invite a pharmacist, wherever he or she may be within the EU, to dispense a prescription written in a language they do not understand, probably about a medication they have never heard of, is nothing short of a recipe for disaster?
Mr Scott: If I may choose my words slightly differently from Lord Trefgarne—

Q207 Chairman: We look to Lord Trefgarne to ask the questions in that way!
Mr Scott: There are major challenges to guaranteeing patient safety in those circumstances.

Q208 Chairman: Yes, that is a very valid issue. Can I ask a supplementary before we move on. We have evidence from the Government that the largest number of patients going abroad under the present arrangement are maternity cases. I wondered if you knew this and, if so, if you had any feedback about what was happening in relation to prescriptions and what-have-you.
Mrs Crawford: I have to say that is not information that the NMC has been privy to, at least to my knowledge. It is an interesting area that deserves further exploration. What we do know is midwifery care across the EU varies greatly. Maternity care systems also are very, very different. If that is the case, it is something that the NMC needs to be aware of and will take away and look into it.

Chairman: It is quite interesting that people are going home to have their babies and it is being paid for.

Q209 Baroness Young of Hornsey: The next question concerns co-operation around e-health. Again, it is about the complexities of that and both of you have commented on it in slightly different terms. Would you consider it useful for e-health standards to be set at EU level, as proposed, in order to achieve the interoperability of information and communication technology systems? Does the development of e-health tools raise any problems of regulation, maintenance of standards, et cetera, and, if so, how do you feel that these could be addressed?
Mr Scott: Again, in a perfect world each country within the European Union would ensure adequate national standards such that it was largely irrelevant where a service was being delivered. As Jill was indicating earlier, the practical reality is somewhat different. When we encountered the problem, for example, of the delivery of radiology services remotely and had to address how we might view that, the conclusion we have come to takes us back to one of our earlier answers: it is wholly impractical for us to attempt to regulate healthcare professionals who are not registered in the UK. That places a responsibility upon those placing the contract for the radiology service to ensure that it can only be delivered in the distant country by properly qualified healthcare professionals. I happen to know that has been a very strong theme within the Department of Health in England and the lead within the Department of Health in England very much has that in her sights.

Q210 Chairman: Do the NMC want to add to that?
Mrs Crawford: I just want to add that we welcome the potential for e-health in terms of sharing information and as being a tool for training and professional development. We do recognise the issues that arise that Finlay has just discussed. In terms of a standard, the standard that we would seek is that it is transparent where the treatment is being delivered because with e-health it may be that it is not always transparent to the patient where the treating professional resides. Clearly for the regulatory systems to be effective it must be transparent to the patient where the person who is treating them is and what regulatory systems apply.
Lord Lea of Crondall: Just as an aside, I am not clear whether you are exaggerating some of the problems. I think that doctors’ prescriptions are notoriously hard to read and you do not seem to be doing anything about that. It seems crazy in an era of modern technology that doctors put your prescription on a computer, but why do you stick to this medieval system.

Chairman: I think that was an aside, not a question.
Lord Lea of Crondall: You might like to answer it. First of all, the GMC are highlighting their call on the European Commission to introduce a legal duty on all medical regulators to share registration information. It is perhaps possible to see where you are coming from, but that is far from operating like an EU driving licence. What is it actually doing? It would still leave Britain to decide what happens in Britain and Poland to decide what happens in Poland. Am I eliding registration and fitness to practise? They are not the same thing, but you have put them in the same sentence in your evidence. It could be that at initial registration 100 per cent of British doctors were given the thumbs-up to be registered in Poland but only 50 per cent of the Polish doctors were given a thumbs-up in Britain to be registered, and I am not talking about any disciplinary issues. Presumably when this body is producing information in the spirit of freedom of information people would have to publish league tables, to coin a phrase, for all European countries. Would you comment on that?

Q211 Chairman: We are really interested to know where the responsibility would lie for all of this.
Mr Scott: My Lord Chairman, may I try and separate two quite different situations, which may help. One is in relation to initial registration and,
broadly speaking, an EEA citizen or someone with
 equivalent rights who qualified within the EEA has
 essentially an absolute right to be registered in the
 United Kingdom. The only qualification to be
 attached to that is that we may refuse registration or
 investigate before granting registration if we uncover
 an existing disciplinary finding in another European
country, and we guard against that possibility by
 insisting on receiving what is generally called a
 ‘certificate of good standing’. There are problems
 around uniformity of the quality of certificates of
good standing, but essentially that provides the
 safeguard. When the certificate of good standing
 produces no problem, we will grant registration. If,
 however, there is existing disciplinary action in
 another country, we are entitled to take that into
 account, but the particular situation that causes us
 concern is different from that. It is where a doctor is
 registered in more than one country simultaneously
 and in one country or indeed in more than one
 country disciplinary action is taken and, because the
 doctor is already registered with us, we would not
 routinely be seeking information from other EU
 Member States, so we depend upon the country
 where the disciplinary action is being taken to notify
 us that it has been taken. Usually, we are very good
 Europeans in this respect and we have excellent
 bilateral arrangements with a number of countries,
 indeed I think now all countries, for the transmission
 of our information. The problem comes in the other
direction where we do not routinely receive
 information about the action taken against doctors
 in other countries so that we can consider action in
 the UK, if they are already registered here, and I hope
 I have explained that difference. That is the point
 of contention and, despite the progress that has been
 made and the acknowledgement of the issue, we
 remain somewhat short of a complete solution,
 although, as I think Claire may want to explain if you
 have time, my Lord Chairman, some progress is
 being made.

Ms Herbert: We increasingly work collaboratively
with other medical regulators across the European
Union and indeed other professional healthcare
regulators to develop voluntary approaches to
proactive information exchange about the
disciplinary records of health professionals.
Unfortunately, the voluntary approach, as Finlay
has suggested, does fall short of the ideal at present
because a number of regulatory jurisdictions are
inhibited from sharing information by virtue of their
interpretation of privacy legislation. Although, I
think, the will is there to share such information,
there are some blockages that we are trying, or hope,
to overcome by virtue of this Directive.

Q212 Chairman: We have run up against this before,
that data protection is being used to block. Could I
ask both of you, what remedies do you think
organisationally there should be for us to deal with
this problem across Europe? It is not only the
certainty of the patient going to mainland Europe,
but it is the certainty of people in this country who are
receiving treatment themselves from doctors from
other countries, is it not?

Mr Scott: Two quick points, if I may. I think, first of
all, that there is a temptation in this country and
elsewhere to over-interpret privacy legislation, and
we regularly encounter that. In fact, when you press,
you find that the legislation is not the impediment it
is sometimes dressed up to be, and of course outside
healthcare there have been some very important
demonstrations of that in, say, the last five years. I also
think, and this is in a sense easy for us to say, that
national governments have to make choices. The idea
of competing goods is not new and governments
regularly have to decide how to resolve the idea of
competing goods, and I think national governments
have to square up to the issue as to where does the
balance lie between the ready exchange of
information to protect patients compared with the
undoubted degree of protection of privacy.

Mrs Crawford: In terms of the remedy, our view is
that the Directive needs to have a legislative
requirement for proactive sharing of fitness to
practise data. This is a fundamental cultural issue in
EU Member States and we have been working very
proactively with other nursing regulators to seek to
achieve some kind of understanding, but there is huge
diversity on this issue within the EU and, therefore,
it would need to be a legislative requirement to share
that registration and fitness to practise information
at an EU level.

Q213 Chairman: So you are suggesting that we
recommend that the Directive makes it clear?

Mrs Crawford: Yes.

Chairman: That would be very helpful to us; it is the
most clear.

Lord Lea of Crondall: I do not think the Directive
says in terms that this would lead to an EU regulator,
but, in a sense, if there were statistical variations in
how many people recognised each other, and I do not
mean in terms of professional qualifications, but this
problem about not registering people, would it not
lead to some sort of demand for a European appeal
and then a European Court of Justice appeal and all
that stuff?

Q214 Chairman: The question of harmonisation.

Mr Scott: Well, again there are no doubt, in principle,
different solutions, but my own view, I think our
view, is that these issues are best addressed nationally
and that is why within the processes and procedures
that we have in place, and I am sure it is true for other
regulators, there are appeal provisions both
internally and obviously to the courts if individuals believe that our actions have been unfair.

Lord Lea of Crondall: I am sorry, but your proposal is that the Director of the Commission should have this role and now you talk about subsidiarity. We all applaud subsidiarity, but here we are, you want to hang on to subsidiarity, but you say that you want it to introduce legal duty and all measure of things to share registration.

Q215 Chairman: It is the sharing of information that the legal duty would be about, would it not?
Mr Scott: Yes, that is correct, my Lord Chairman. The history is that there is a provision which amounts to “may share information”, so it is permissive and it is “must” that we would both want to see.

Q216 Chairman: Yes, so it is the sharing of information rather than the harmonisation of regulation because that might be minimum standards which you would not want at all.
Mr Scott: A point, I think, very well made by our colleagues from the NMC.

Q217 Lord Trefgarne: Am I right in understanding that, for any national with an equivalent qualification who presents themselves for UK registration, you are required to register, subject to a disciplinary clean sheet, regardless of any other consideration?
Mr Scott: My Lord Chairman, there are essentially three categories of doctors. One is UK graduates who, irrespective of nationality, are essentially entitled to registration, subject to the test that Lord Trefgarne has identified, that there is no reason to believe they are not fit to practise. The second group is EEA citizens or those with equivalent rights who qualified in other parts of Europe essentially are treated as though they were UK graduates. The third group is doctors from outside who qualified outside Europe where we have a discretion on whether or not we should register. Those essentially are the three groups, so it means that, at the risk of repeating myself, for UK doctors and EEA qualifying doctors, there is tantamount to an absolute right to seek registration.

Q218 Lord Trefgarne: Are you satisfied that all those who present themselves, no matter which of the 27 EU nations they come from, meet the required standards, but you are required to accept anyway?
Mr Scott: My Lord Chairman, I think our longstanding position has had two strands to it. The standards laid down in Brussels amount essentially to input standards, that doctors should cover so many hours and should cover so many topics, and we have long argued that regulation should be based on evidence of outcomes or competences, and the fact that that is not the case is undoubtedly a weakness. The second strand, which is long-running, is that we are not entitled in law to assess the language competence of doctors from other parts of Europe, and we regard that, as a matter of principle, to be unacceptable. We are entitled to insist that doctors from outside Europe can communicate effectively in English, but we are not able to do so for European doctors.

Q219 Chairman: We are going to come to language, but I just want to ask Mrs Crawford if she has anything else to add on this?
Mrs Crawford: Simply to say that the situation is entirely the same for nurses and midwives, that we are under the same requirement, we have the same considerations and we have the same concerns.

Lord Trefgarne: It is rather terrifying, is it not, that there may be doctors coming in who, given a total freedom, would not have registered, but you are required to do so?
Chairman: Lord Trefgarne, we will move on now to language. I think your point is very well made.

Q220 Baroness Gale: The language issue, I believe we all think, is a very important issue in the provision of cross-border healthcare. The NMC have noted in their evidence that the difference in language on EU prescriptions could lead to putting the patients at risk, and it is their view that patients should receive care in a language that they are familiar with. Therefore, in the European Union that has 23 official languages—let alone the unofficial languages like Welsh, for example, which is the first language in many parts of Wales and there may be other countries very similar to that as well—that issue has to be taken very seriously and it is very important for patient safety. Whose responsibility do you think it should be to address the language barrier both in terms of arranging and funding any necessary translations and interpretation?
Mrs Crawford: I think this is a very difficult issue. I think that the basic right of patients to understand what is being said to them about treatment to give informed consent is one that cannot be waived and, therefore, that is what underpins the NMC view that patients have a right to receive care in a language that they understand. In terms of the responsibility for funding, I think it is a difficult one, but it is not a regulatory one. In terms of accountability, we would hold professionals responsible for the care that they deliver to a patient and, in order to deliver to that patient, they need to be able to communicate with that patient, to understand the symptoms, to explain the treatment that they are going to provide and to secure informed consent, so I think it is very difficult.
but each individual registered professional will carry a responsibility for the treatment they deliver to an individual and a responsibility for being able to communicate with that patient. How, in practice, that is addressed and who funds those translation services is a very real issue and it is not one that I can offer an NMC view on, but what I can say is that we are very clear that patients need to be in a position to understand what is being done to them and to give informed consent.

Q221 Chairman: It is going to be very difficult to achieve that.
Mrs Crawford: It is.

Q222 Baroness Young of Hornsey: That is not a new issue, is it? For example, we are fond of saying in London that there are approximately 300 languages spoken, so would you hold the same right for people across the country?
Mrs Crawford: Well, our regulatory standards are clear that, when a nurse delivers care, they need to be able to secure informed consent from that patient, and there is a responsibility. Clearly, in an emergency situation you put the interests of the patient first, but there is that responsibility already within the regulatory systems, that professionals do secure informed consent. It is not a new issue, but what is interesting about this Directive is that it will facilitate EU nationals to come to this country and vice versa and will present further demands in terms of translation services, and the NMC view would be that the patient has to be able to communicate and give informed consent. Even if they have done that in their home country in a language which they understood, complications may arise and situations may arise where they need to be able to communicate and understand in order to give that consent.

Q223 Baroness Young of Hornsey: I understand that, but I am just wondering if there are some lessons that we can learn from our experience already that can be applied to this so that it is not an insurmountable problem?
Mrs Crawford: I think some of the work that NHS Choice has done in terms of translating information electronically has huge scope, and it is not an area for the NMC to lead on or to take a view on, but I do think that there are ways of addressing at least some of the challenges.

Lord Wade of Charlton: My Lord Chairman, I cannot help commenting that veterinary surgeons provide a marvellous health service to animals without being able to communicate! You ought to be able to develop a skill of having a pretty good idea of knowing what someone is suffering from without talking to them about it!

Baroness Neuberger: There is no ethical requirement for consent from animals though! It does make a difference!

Q224 Chairman: Mr Scott, you have said quite a few things about language. Is there anything else you want to add at this point?
Mr Scott: No, only to underscore the point, I think, Jill has made. There is an absolute duty on doctors registered with us to ensure that they have secured informed consent, and that does raise the kind of language issues which Baroness Young has raised in London, for example. The health service of the country concerned, in our case the UK Health Service, has to respond to that requirement.
Chairman: Otherwise things go wrong. We now move to Lord Trefgarne who is going to talk about indemnity.

Q225 Lord Trefgarne: You have made it clear that you insist upon adequate professional indemnity to be backed up by insurance, which of course is entirely right and proper, but clearly the arrangements for professional indemnity and professional insurance across the EU are far from standard, and indeed I am told that discretionary insurance is available only in a minority of Member States: the UK, Ireland and Malta, leaving 24 where they do not have it. What problems do you think this will generate and what suggestions can we make to overcome them?
Mr Scott: Again, if I may distinguish two circumstances, it is not currently in force, but the Medical Act 1983 has been amended so that at a future point, probably from 2009, it will be a condition of holding a licence to practise that a doctor has adequate and appropriate insurance or indemnity, and it is, I think, notable in this context that Parliament saw fit to admit both the possibility of insurance and indemnity, and that reflects the fact that in the UK there is a long history of successful protection of patients through indemnity as well as insurance. A challenge that we face when we activate that requirement next year concerns doctors who move to the UK from other parts of the EU and wish to rely upon their existing professional insurance or indemnity, and I think there have to be questions asked about the confidence we can have in indemnity provided from other countries because, by definition, indemnity is not regulated whereas the insurance market is regulated. My Lord Chairman, that is not an issue we have yet managed to resolve, not least because, if we insist that, for example, indemnity from outside the UK is not acceptable, I think that would lead us to conflict with the Commission in relation to freedom of movement. I think that has to be distinguished from the arrangements made by organisations or healthcare providers to ensure that
patient interests are protected. For example, as I imagine you are aware, we have in the UK the NHS Litigation Authority which provides Crown indemnity, not based upon individuals, but based upon NHS units of provision, and the reality is, therefore, that, when we introduce the new requirement next year, large numbers of doctors will be able to meet the requirement not through personal insurance or indemnity, but relying upon the Crown indemnity provided by the NHS. This means that what is absolutely required is information for the patients of the kind that Jill was describing which makes it clear to patients who are considering moving their healthcare whether they will be protected by individual insurance or indemnity or, as it were, organisational insurance or indemnity, and it is very important that the patient understands the position. 

Mrs Crawford: The indemnity issue is one that the NMC has a particular challenge around. The NMC recommends indemnity insurance for its registrants and we recognise its very significant role. However, we do make the difference between patient safety and financial compensation, and I think the standards and the professional standards are the key issue from a regulatory point of view. However, we do have a particular issue in relation to midwifery whereby some of our registrants, independent midwives practising independently, are not able to secure indemnity insurance on the market at all and, therefore, the NMC had a very robust discussion two or three years ago about whether to recommend or require indemnity and it came down on the side of not removing independent midwives from our care provision because they do provide services to some very vulnerable women who may not access healthcare otherwise. The Department of Health are working very actively with the Independent Midwives’ Association to seek a solution to this possibly under the social enterprise model, so we do have a particular issue in this area and, if the Directive makes it an absolute, there is an issue within the UK for this group of independent midwives. It is currently a small group, but also within the policy direction within the UK there is a move for more midwives who work in an independent and autonomous way outside acute trusts and, therefore, there does need to be some UK resolution of how those practitioners are indemnified so that women are not left at risk.

Chairman: That is a question we may want to come back to you on.

Q226 Baroness Neuberger: I need to declare an interest: I am a former lay member of the GMC. When I read the evidence, you, the Nursing and Midwifery Council, make it very clear in your written evidence that the rules that apply to the recognition of professional qualifications are not clear, but actually you do not say the same, the GMC. I think, so let me start with the NMC, but really I want you both to answer it. What is your view on the provisions in the proposed Directive relating to the recognition of professional qualifications? We have had a bit of a dance around this already, but, first of all, do you think that the lack of clarity identified by the Nursing and Midwifery Council needs to be addressed and, if so, how?

Mrs Crawford: I think the clarity that we seek which is in the Directive and which must not be removed is that the place where treatment occurs is where the regulatory systems kick in, and that clarity needs to be there and it is there. There is an issue around the recognition of professional qualifications, which was in the former Directive which makes it slightly complex, whereby, if somebody provides services in another EU State on a temporary basis, they remain registered with their home EU State and, therefore, that confuses that issue, so, if you are going to use the regulatory systems where the treatment was delivered, but that professional is registered in the UK, we have a problem.

Q227 Baroness Neuberger: It is a real issue at the moment, is it not, with some local provision of GPs? There are people coming from Germany to provide services and they are coming for the weekend.

Mrs Crawford: It is only a problem if we have not got clear standards between regulators for the transfer of information and for collaboration. It may be that the GMC wish to add to this point.

Mr Scott: To go back, I think, to the core issue, I think the problem around the freedom of movement of individuals for us is not a lack of clarity, but a lack of adequate balance between the interests of the professional who wants to move and the protection of patients within the UK, in our case. I think that is the challenge and it is one where we have had a very constructive alliance with our colleagues in the other healthcare regulators to try to resist some of the proposals that have emerged from Brussels in the past two or three years, and we very much value the requirement that, if a doctor wishes to practise in the UK for however short a period, then they must register with the GMC so that the clear line of accountability that we discussed at the beginning of this session remains in place.

Q228 Baroness Neuberger: And you have made that point very forcibly no doubt?

Mr Scott: I think we have been boringly forcible in relation to it.

Baroness Neuberger: That is precisely what I wanted to hear.
Chairman: We are going to move on to prior authorisation, which might be a way of dealing with some of these issues.

Q229 Baroness Morgan of Huyton: Obviously one of the things the Commission looks at is the idea of prior authorisation, particularly for hospital care, and it has a package of ways that that has to operate, that it has to be proportionate, it has to be non-discriminatory, but at the same time it has also got to take account of what is happening in the Member State, so in a sense obviously it has to take account of the Member State’s social security system and the organisation of care in that Member State and whether a large movement of patients could have an impact on the Member State. Really I want to know what is your view of the proposed system and whether you think it is going to help, whether it is adequate, and do you have any suggestions about how it should be operated in any different way?
Mrs Crawford: It may not be helpful, but the NMC view is that it is an NHS and Department of Health issue rather than a regulator issue.
Mr Scott: Again, my Lord Chairman, I do not think we would want to comment on the particular issue of prior authorisation.

Q230 Baroness Morgan of Huyton: Because, in your view, it relates only to finances?
Mr Scott: I think in any discussion around patients and patient safety, it is important to keep emphasising the need for adequate regulatory arrangements, but, having made that point, how the finance system operates, I think, is not for the regulator per se.

Q231 Chairman: But the way it is agreed in relation to who makes that authorisation at the first step, which might be a medical recommendation, might be something you would want, so it is how the medical recommendation fits into the whole structure because that is where there is one layer of protection.
Mr Scott: I am not sure it is a matter for the Directive per se, but in terms of information for patients, we would want to continue to stress the value of only acting under advice from your own UK-based medical practitioner, whether that is a GP or someone else. The idea of health tourism, whether it is within Europe or wider, carries huge risks for patients, so we would very much stress the need to draw upon your existing source of medical advice before making any decision. Allied with that, and again I am sure it is true for the Nursing and Midwifery Council, we require doctors, if they are going to delegate or pass on responsibility for care, to ensure that they do so only under circumstances which protect patients by, in effect, requiring that the

Q232 Baroness Morgan of Huyton: How would you do that now? If a patient came to a doctor in the UK now and said that they wanted to go to Spain for a particular treatment because they thought they would get it more quickly or whatever, how would that operate now? How would the doctor find the relevant information in order to give sensible information to their patient?
Mr Scott: My Lord Chairman, I think you could describe an ideal where the doctor has the time to consult colleagues and so on, but I think the reality is that many GPs or other doctors in those circumstances would say that they could not be confident that they can access adequate information in another country and would, I hope, very much point out the risks, therefore, of engaging on an enterprise with such large gaps in the information base.

Q233 Lord Wade of Charlton: My question was going to be on what you consider to be the potential disadvantages, but, as I can tell so far, you have already illuminated every subject we have discussed as being a disadvantage, so we have identified what are the problems. Could I then turn the question a bit the other way. On balance, is this something that we should do or not? Do we support this Directive, but with some of the reservations that you have made, or do you see that the disadvantages are such that it would be better to leave well alone?
Mr Scott: I think we are probably in the fortunate position of, as it were, not having to take a view.

Q234 Lord Wade of Charlton: Yes, but we do!
Mr Scott: If I may go on, the reality of life in 2008 is that there is a great deal of travel within the European Union, whether for pleasure or business purposes, so citizens of the UK frequently travel to other countries and travel in the other direction is clearly commonplace, so I think that, whether you talk about health tourism or something else, what we need across the European Union are adequate arrangements in all countries to protect patients and I think that amounts to trying to get an interlocking system that addresses three requirements. One is about the regulation of healthcare professionals, the second is about the regulation of healthcare providers and the third is about the provision of adequate information to facilitate movement, whether it is health tourism or for business or pleasure purposes. I think that the weakness, if there is a weakness, is that each of these things is viewed, as it were, in isolation without it being evident that anyone is taking an overall view of whether those
components interlock in a way that addresses all the risks for patients and patient safety.

Q235  **Lord Wade of Charlton:** So, to sum it up, you would say that you think that the scheme is basically a good one, but that we have to take steps to make it much easier for people to travel about Europe, but there need to be an awful lot of safeguards and changes, improvements, if you like, built into the existing Directive to draw attention to the issues that you have discussed today? Would that sum it up?

**Mr Scott:** I could not put it better, Lord Wade.

Q236  **Lord Wade of Charlton:** Would the NMC view be somewhat similar?

**Mrs Crawford:** It would be very similar. We welcome it on the basis that it provides clarity to patients. Patients will, and do, access healthcare across the EU, so we welcome it on that basis. I also think that there is a real opportunity to strengthen regulation across the EU via this Directive if the chapter on co-operation is expanded to be very clear that it relates to regulatory systems and the individual EU regulators; it could be a very significant step forward in terms of regulation and patient safety in the EU.

Q237  **Lord Trefgarne:** Against all this background of shortcomings, is it not possible to say at the end of the day that most of the healthcare professionals in Europe are hard-working, well-qualified and do their best?

**Mr Scott:** My Lord Chairman, I would want to confine myself to saying that the great majority of doctors in the UK are very good doctors who deliver high-quality healthcare.

Q238  **Lord Trefgarne:** So in the other 26 Member States they may not be?

**Mr Scott:** And I would include in my general statement that the 22,000 doctors who qualified elsewhere in the EU make a very important contribution to healthcare in the UK. Such data as we have does not point to any general problem, but the reality is that, for the reasons we discussed earlier, regulatory standards vary enormously from one country to another and the way in which the standards are expressed in the relevant Directives does not ensure, in our view, a uniformly high standard of competence across the EU.

Q239  **Baroness Morgan of Huyton:** I am not asking you to name and shame here, but are you clear in your minds, as professionals, which are the countries which, in your view, do not have clear regulation and which do, or which have sufficiently high standards of regulation and which do not?

**Mr Scott:** I think it is evident, from examining the regulatory systems in the other countries, that there are diverse approaches and, in our view, the UK is an example of a regulatory regime that takes very seriously the need to ensure that those registered remain up-to-date and fit to practise throughout their career, and that is not the case elsewhere.

**Lord Lea of Crondall:** Is it not the case, looking across Europe, that there are some countries with a higher life expectancy than Britain and some countries with a lower life expectancy?

Q240  **Chairman:** Can I just pick up Lord Lea’s point and say that we have been talking about co-operation and hearing about standards and different demographic patterns, if you like, which is the point Lord Lea makes, and really we are very interested in what co-operation both your organisations have across Europe and where you gain your information and where you share experience and expertise, so maybe you could pick up in this question some of the issues about how you gain that information and how you make use of the kind of demographic question Lord Lea is asking about.

**Mrs Crawford:** The Nursing and Midwifery Council in recent years worked with some other European nursing regulators to form FEPI, which is an organisation which brings together European nursing regulators and seeks to achieve collaboration and links between those regulators, and we were instrumental in achieving that network and we are working very hard currently to make it effective. What our engagement tells us is that there are very, very different standards, but there is also a will amongst those nursing regulators to come to some kind of commonality and there is also a sense that the UK does do regulation well and that they would like to work with us on some of the common principles of regulation. The links are less formal within midwifery, but we are seeking to establish those links, and we also work via CEPLIS which brings together the liberal professions, and we have engaged with them on the issue of continuing professional development and looking to see whether we cannot agree the principle of continuing professional development at a European level in order to enhance patient protection, so it is an area where we are very active, we have a specific EU Department and we are seeking to engage and establish networks, but there is work to be done still.

**Mr Scott:** I will not take your time by describing the extensive steps we take to improve co-operation, but we have very good bilateral relations with a number of countries, including the Nordic countries and the Netherlands, and Claire led for us a very successful project which we were invited to undertake by the Department of Health in England on health...
professionals crossing borders, and we would be delighted to send a supplementary note describing that.

Q241 Lord Lea of Crondall: But you have no EU body like the Nursing and Midwifery Council has? Ms Herbert: There is an organisation convened by the French Order of Doctors which brings together medical regulators on a regular basis to discuss these kinds of issues, but I think the work that we have done through Healthcare Professionals Crossing Borders to bring all regulators, not just medical regulators, together has really helped matters.

Chairman: Can we accept Mr Scott and Ms Herbert’s offer to send us a note about that because that would be really helpful to understand how that cooperation takes place. I am going to have to close the session because we have already gone over time, which shows how interested the Committee has been in what you have said to us. We are immensely grateful for your engaging in the discussion with us and, as you can hear, we are raising probably some of the same questions you may have in your own heads. If you want to send anything else to us, do write because what you have said to us so far has been immensely valuable. Thank you very much indeed.

Supplementary memorandum by the General Medical Council

1. During the General Medical Council’s oral evidence to the Committee on 20 November 2008, we committed to sending the Committee a supplementary note on Healthcare Professionals Crossing Borders in response to Question 11.

2. The Healthcare Professionals Crossing Borders initiative aims to make a contribution to patient safety and high quality healthcare in Europe through effective collaboration between European health regulators (competent authorities).

3. The initiative began as a patient safety initiative of the Department of Health in England during the UK Presidency of the EU in 2005.

4. The GMC, together with other UK professional healthcare regulators worked closely with DH(E) during 2005 to build engagement with regulators across Europe and to develop a programme of collaborative work on regulatory information exchange. At the end of the UK Presidency, the GMC was invited by DH(E) to takeover the leadership of the initiative on a longer term basis to further develop informal regulatory collaboration and raise the profile of regulatory issues Europe-wide in the context of professional mobility and patient safety.

5. The initiative brings together regulators from across the European Economic Area (EEA), and relevant EU-level networks and associations, to identify and implement collaborative approaches to professional healthcare regulation in the context of free movement of healthcare professionals in Europe.

6. The increasing mobility of health professionals and patients in Europe means it is vital that regulators, patients and citizens have assurance that all health professionals are fit and safe to practise. There are immense benefits to health systems in Europe and the health of European citizens from the free movement of health professionals. There is also the potential for patients to benefit from access to treatment in other European member states, where free movement rules allow.

7. Regulators must work together to contribute to high quality health care in Europe. This is achieved by promoting professionalism and excellence through developing effective domestic regulatory systems and procedures and ensuring there is appropriate cooperation between regulators in the context of professional free movement. This includes sharing information on standards of medical education and practice and ensuring those professionals who are, or may pose, a risk to patients cannot move between countries without regulators being alerted to their disciplinary and practise record.

8. The work of the initiative is set out in the Edinburgh and Portugal Agreements.

9. More information about Healthcare Professionals Crossing Borders can be found at www.hpcb.eu

24 November 2008
Introduction

1. The NHS European Office, which is part of the NHS Confederation, is currently conducting a consultation to obtain members’ views on the European Commission’s proposals for a directive on the application of patients’ rights in cross-border healthcare. This exercise should help us to better understand potential implications for the NHS. The following comments are based on our initial analyses of the text, and, pending the outcome of the consultation process, may be subject to change.

The need for EU Action and its Objectives

2. In considering the proposals, it is important to be aware that rulings in the European Court of Justice (ECJ) have already established that patients have certain rights to access healthcare in other EU countries. These rights cannot be removed. There are, however, a number of uncertainties which make the case law difficult to implement in practice. To the extent that it could clarify the present situation, for the benefit of both patients and those delivering health services, we think a directive could be helpful. However, we are concerned that any EU legislation must respect the principles of subsidiarity and proportionality and should not interfere unduly with the organisation, funding, and delivery of healthcare, which remains a national competence.

3. We recognise that there may be circumstances where patients could benefit from receiving treatment in another EU member state. However, we know that most patients prefer to be treated close to home. Although some patients will be interested in the possibility of cross-border healthcare, bearing in mind the inconvenience and costs associated with travelling for healthcare and possible language barriers, it seems unlikely that large numbers of UK patients will seek healthcare abroad.

4. In view of this, it is important that systems established to provide for and facilitate cross-border healthcare are not disproportionate in scale and cost to the level of cross-border activity and do not have wider, unintended, consequences for health systems as a whole. We do not believe that the promotion of cross-border healthcare should be an objective in itself. Rather, the objective should be to provide clarity about the rules relating to cross-border healthcare so that interested patients are able to make informed decisions within a framework that respects the organisation and structures of different health systems.

Conditions on Access to Treatment Abroad

5. We understand the current EU framework, and the proposals in the draft directive, to be based on the principle that patients should be eligible for reimbursements towards the costs of healthcare received in another EU country only to the extent that they would have received the same healthcare at home. So, for
example, if a PCT had decided not to fund a particular treatment for an individual patient, the patient could access that treatment in another EU country, but would have to pay for it themselves and would not be eligible for a reimbursement towards the cost. We think this principle is correct and it is crucial that it is preserved.

6. In relation to this, it is important to understand that many health systems, including the NHS, do not have national level eligibility criteria for determining access to particular treatments or a defined “basket of care” which all the people they cover are automatically entitled to receive. The treatment which an individual can receive is often determined at a local level, based on their particular health needs balanced against the health needs and priorities of the wider local population. The directive must provide for such local decision-making processes to continue.

7. Where it has been established that a patient is eligible to receive a particular treatment and they elect to receive that treatment abroad, reimbursement is limited to the amount that the same treatment would have cost the home system. The patient must meet costs up front, and must cover costs that would not be incurred if they were treated at home, such as travel costs. If treatment is more expensive abroad, the patient must cover the difference. If, however, treatment is cheaper abroad, the patient cannot be reimbursed more than they have paid—ie they cannot make a profit. We believe this approach is correct, as a patient’s choice to be treated outside the UK should not lead to higher costs for the NHS, thereby reducing the resources available for the wider population.

8. The draft directive envisages that reimbursements could only be made conditional on having obtained prior authorisation (ie the requirement for a patient to seek the agreement of their home health system to them receiving treatment abroad) in exceptional circumstances. We are disappointed that the draft directive does not recognise the value that prior authorisation systems can offer to patients in terms of providing them with clarity on matters such as what reimbursements they will be eligible for and what costs they will have to meet themselves, arrangements for any after-care needed and what will happen if anything goes wrong.

9. It is essential that patients who do seek treatment abroad understand the conditions that will apply, both in terms of quality and safety and financial arrangements. In view of this, we consider that a case could be made for allowing prior authorisation systems to be mandatory for all patients seeking care abroad, provided these systems met criteria such as transparency and proportionality, were simple and straightforward for patients to use, and gave timely responses to requests.

10. We are examining the question of when it might be appropriate to refuse prior authorisation as part of our consultation process. Concerns have been raised about patients travelling abroad for treatments with major implications in terms of aftercare or potential complications which may fall upon the NHS. Prior authorisation systems could be useful in such cases in clarifying, for example, whether aftercare would normally be provided by the NHS as part of the “treatment package”.

11. Other situations when it might be appropriate to restrict a patient’s right to travel to obtain healthcare include: patients with a highly contagious and dangerous infectious disease, patients requiring care in a secure psychiatric facility, and prisoners. Any patient refused access to treatment abroad should be able to obtain a clear explanation of how and why the decision had been reached.

**Practical Impacts of the Proposals on the NHS**

12. Unless there is a very significant increase in the number of patients accessing cross-border healthcare, which current indications do not suggest, the practical impacts of these proposals on the day-to-day provision of healthcare in the UK are likely to be small, particularly, for example, when compared with the impacts of ongoing trends in migration.

13. The exception to this is likely to be for local commissioners, who will need to be able to respond to queries regarding eligibility requirements, level of reimbursements and processes for obtaining prior authorisation, where this is required. Clearly, the nature of the legal framework put in place by the directive will be important in determining how complex and burdensome this will be.

14. In our view, a system providing for patients and commissioners to discuss arrangements before treatment is obtained abroad would be preferable. Although this would imply additional work for commissioners prior to treatment being obtained, it should reduce risks for both parties at later stages, eg disputes over reimbursements or whether a treatment was necessary.
15. Although not directly affected by provisions on cross-border healthcare, discussions in this area also highlight questions about eligibility to NHS funded healthcare. Under current arrangements, it can be extremely difficult for commissioners to determine an individual’s entitlement, for example, in the case of individuals dividing their time between the UK and another EU country.

16. There are also challenges, relating to both incoming and outgoing patients, in terms of calculating the “NHS cost” of care, particularly for treatments not subject to tariff, or where packages of care need to be “unbundled”. In general, clear guidance on the legal framework and its application in the NHS will be needed to support implementation in NHS organisations.

**Equality of Access to Cross-border Healthcare**

17. The issue of equality of access is challenging. For example, geographical factors will mean that some individuals will be able to access cross-border services more easily than others. Some patients may not be fit, or for other reasons, able, to travel to obtain treatment. Since patients will need to pay for treatment up front, and will normally need to cover travel, accommodation and other costs which would not be incurred if treatment were provided at home, there will be financial barriers which are likely to limit some patients’ access to treatment abroad.

18. Existing social security arrangements already provide a mechanism (the “E112 referral”) under which the NHS directly funds planned treatment in other EU countries. This system is often used for NHS patients whose treatment cannot be provided in the UK, although NHS patients can also apply for an E112 referral in other circumstances. In particular, if a patient is experiencing “undue delay” in receiving healthcare under the NHS and they wish to be treated abroad an E112 referral cannot be refused.

19. Where treatment can be provided in a timely manner in the UK and patients are deciding for personal reasons to seek treatment in another EU country, we think it is reasonable that, as a general rule, they should be responsible for costs which would not be incurred if they received NHS-funded treatment in the UK.

**Requirements Relating to Information on Cross-border Healthcare**

20. All patients should be able to obtain information about their options, including treatment abroad, in a format that is clear and understandable to them, and enables them to make informed decisions about their healthcare. Ideally, information on cross-border healthcare should not be provided in isolation, but as part of a wider strategy of information for patients and the public about health and healthcare.

21. As such, it is important to place the responsibility for provision of information on cross-border healthcare at the appropriate level and be realistic about what sort of information different actors will be able to provide. For example, the idea of a network of national contact points may be a useful approach, but it is important to be clear that these contact points cannot give personal advice on the best care, or act as advocates, for individual patients.

22. Conversely, whilst a patient’s own clinician is likely to be best placed to help them make choices about their care, and their local NHS commissioners should be able to provide advice on issues such as local eligibility criteria, it would be unreasonable to expect either to give detailed advice on how other countries’ health systems operate.

23. It is also important that provisions relating to the availability of information and data collection on cross-border healthcare should not place new costly, bureaucratic burdens on NHS organisations.

**Provisions Relating to Cooperation in the Field of Healthcare**

24. The Commission’s proposals also include a number of provisions designed to promote cooperation between EU member states, in areas such as the establishment of European reference networks of healthcare providers, e-health and the management of new health technologies. These three areas are already the subject of existing cooperation at EU level, and we have not yet seen evidence to suggest that it is necessary and appropriate to provide a legal basis for this work. We will be considering what the implications of doing this might be, in particular, with reference to subsidiarity.

*25 September 2008*
Memorandum by the Royal College of Nursing

1.0 INTRODUCTION

1.1 The RCN welcomes the proposed introduction of a clear legal framework for the application of patients' rights in cross-border healthcare in the European Union. The right to access care in another EU country already exists under EC regulation 1408/71¹ on the application of social security schemes and under Article 49 of the EC treaty on free movement and access to services and the subsequent interpretations of these provisions by the European Court of Justice (ECJ)².

1.2 However, given that the application of these rights has been largely determined by individual court rulings, this has created a piecemeal approach, a lack of clarity for patients and professionals, and an absence of agreed EU systems to ensure safe cross-border care.

1.3 For this reason the RCN believes that the objective of the EU’s proposed directive should be to:

1.4 Clarify existing rights and ensure these are easily understood, equitable, and enhance patient care,

1.5 Ensure they do not undermine domestic provision and financing of health services,

1.6 Ensure that patients have access to appropriate information in deciding whether to seek treatment in another EU country,

1.7 Provide clarity on which country is responsible for the quality and safety of care and redress if anything goes wrong.

2.0 INTRODUCTION

2.1 With a membership of over 390,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nurse cadets, the Royal College of Nursing (RCN) is the voice of nursing across the UK and the largest professional union of nursing staff in the world. RCN members work in a variety of hospital and community settings in the NHS and the independent sector. The RCN promotes patient and nursing interests on a wide range of issues by working closely with the Government, the UK parliaments and other national and European political institutions, trade unions, professional bodies and voluntary organisations. The RCN welcomes the opportunity to contribute to the House of Lords Select Committee on the European Union Inquiry in the European Commission’s proposed directive on the application of patients’ rights in cross-border healthcare.

3.0 PATIENT MOBILITY

3.1 There is very limited data on cross-border care in the EU, but the European Commission’s impact assessment estimates it accounts for about 1% of public health expenditure in the EU (including emergency treatment whilst temporarily in another EU country).³ The level of cross-border care also varies across Europe with much taking place in border regions.

3.2 About 4% of those surveyed in the European Commission’s Eurobarometer survey of 2007 had received care in another country in the last twelve months and 54% of those questioned would be open to travel to another EU country for treatment, particularly if a treatment were unavailable at home.⁴

3.3 Nevertheless, UK surveys have shown that patients would prefer to receive high quality care close to home and choice over treatment options rather than location of care. Whilst hospital infection rates and waiting times were important, communication with staff, ease of access and transport concerns were a priority for a majority of patients in a recent NHS Choices survey⁵. That same survey also suggests that people were broadly happy with the hospital they went to, whether they’d had a choice over a different location of care or not. So it is important that any EU legal framework does not undermine member states ability to provide these services locally to their population.

3.4 A recent report on Assuring the Quality of Healthcare in the European Union⁶ identified a range of reasons why patients seek treatment in another EU country. In some cases they may already be abroad (eg on holiday, retired) in others they travel to another EU country explicitly to seek treatment (eg for convenience when living

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¹ Council Regulation (EEC) No 1408/71, 14 June 1971 on the application of social security schemes
² In particular cases C-158/96 Kohll [1998], C-120/95 Decker [1998], C-368/98 Vanbraeckel [2001], C-157/99 Smits and Peerbooms [2001], C-372/04 Watts [2006]
⁴ Flash Eurobarometer Survey #210, 2007, Cross-border health services in the EU; Analytical Report
in a border region, being sent for specialist treatment by their home system, on a patient’s own initiative). The report also provides some evidence from surveys of patients who have experienced cross-border care and how they rated the quality of that experience. These include patients from the London Patient Choice Project who were sent to five hospitals in Belgium (2003–04).\(^7\) Most were very satisfied with their care but there were a number of challenges—including linguistic/socio-cultural barriers, and issues relating to distance, travel, and continuity of care. It should be noted that most of the cross-border care studied was planned and in some cases there were detailed contracts between providers.

### 4.0 The Proposed Directive

4.1 Under the proposed directive, member states will need to define clear quality and safety standards and monitoring systems to ensure that health care providers monitor and meet these standards. The RCN strongly supports the introduction of this framework and the clarification in the proposed legislation that requirements in relation to quality, safety and liability applied to cross-border care should be those of the country where the treatment occurs, not the home country. This gives clarity to patients and means that any treatment received in the UK follows UK regulatory requirements.

4.2 The RCN also welcomes the proposals in the directive to introduce supporting measures through “national contact points” to ensure that patients have access to information on how to navigate the system, on care provided, cost and outcomes. It is important that this information, as with any health information, is reliable, comparable and adapted to the users, particularly as there may be commercial interests from some health care providers in attracting patients.

4.3 The proposals do not refer explicitly to the information needs of health professionals. These need to be considered given health professionals’ roles in advising patients, and assisting in interpreting information.

### 5.0 Authorisation and Payment

5.1 The draft directive confirms previous Court of Justice rulings that patients should be able to access outpatient care in another member state and seek reimbursement for these costs. It also proposes that generally patients should be able to seek hospital care without prior authorization. The proposals do not affect a health system’s right to apply conditions for access to health care such as needing to be referred through General Practice for specialist treatment. This is an important principle for the UK, which the RCN would wish to see maintained.

5.2 The RCN supports the requirement for countries to have transparent systems and time limits for responding where prior authorisation is sought—this is particularly important if the motivation for seeking treatment abroad is “undue delay” when the patient may be experiencing significant pain and discomfort.

5.3 As long as there are clear and transparent decision making processes and reasonable justification, the directive should allow for some variations in what is funded amongst different localities and countries of the UK, to reflect local priority setting.

5.4 It is unclear whether the current proposals allow countries to introduce a general requirement for prior authorization for non-urgent hospital care, or whether it needs to be on a case by case basis, if funders have concerns about the outflow of patients causing a serious risk to financing and planning of services.

5.5 The RCN is concerned about a system where patients pay up front for hospital care and then seek reimbursement which is likely to involve significant initial costs for the patient. This could discriminate against patients with limited resources. The RCN would argue that in cases where prior authorisation is sought for treatment there should be a direct transfer of payments between funders and this should be made explicit in the proposal.

5.6 The RCN agrees that in the majority of cases reimbursement should be provided up to the level of the costs of that care under the home health system. We believe that patients seeking treatment outside the UK by choice should not expect to place an added financial burden on the NHS. In any case the current system (under EC regulation 1408/71) remains in place whereby a home health system can decide to pay the full costs, where it has decided that it is better to treat a patient in another country.

\(^7\) See above pp70–72
6.0 OTHER PRACTICAL IMPLICATIONS IN THE UK

6.1 Top up Funding

6.2 Since patients from the UK choosing to seek treatment in another EU country would only be reimbursed up to the cost of the treatment at home, the UK will need to be clear about whether a patient receiving funding from the NHS can make top-up payments, without forfeiting their NHS funding:

6.3 To cover the added cost of similar treatment in another country,

6.4 To cover additional treatment/aftercare,

6.5 Or to cover drugs for which the patient has a prescription, authorised by a clinician in another member state, but which would not normally be covered by the local funder in the UK.

6.6 Currently the position is that a UK citizen cannot be both a private and a NHS patient for the treatment of one condition during a single visit to a NHS organisation8. In other words, if a patient chooses to top up NHS care with private payments for treatment then they would also have to pay for all NHS treatment related to that diagnosis—this can inflate costs from around £2,000 for a course of treatment to around £20,000 for full package of care9. There are several specialist drugs that are widely used in other parts of the EU, particularly in cancer care but which are not approved by NICE for use in the NHS. This has caused the public considerable concern and in response a review was led by Prof Richards on the use and impact of top up payments in NHS cancer care10.

6.7 In its response the RCN has argued that top up payments per se create gross inequalities in care provision and may even divert resources from a state funded patient to a private payer. However we have great sympathy for the sense of inequity that some UK patients express where they could easily get life prolonging therapy in other parts of the EU but not in England. We believe that attention should be on the authorisation processes for NHS funded care and not on the development of another layer of complexity for patients to navigate.

7.0 COSTING TREATMENTS AND MEASURING OUTCOMES

7.1 The proposed directive will require member states to have a mechanism for calculating costs to be reimbursed that should be based on objective, non-discriminatory criteria known in advance. Given that some aspects of the treatment may be provided in another country, and aftercare provided on the patient’s return to the UK, funders will need to be able to clearly identify the costs of different elements of care.

7.2 Currently, NHS England uses Healthcare Resource Groups to quantify and allocate resources to episodes of care, but there are different funding approaches in Wales, Scotland and Northern Ireland. The NHS England activity based payment system, Payment by Results (PbR), uses a fixed price tariff weighted for case mix but only in the main with hospital based activity although there are plans for a tariff for community and mental health care.

7.3 Whilst we recognise that internationally many health systems use “casemix adjusted” payment methods to fund hospital activity, they are all distinctly different and each operates within different allocation and commissioning systems. Great care will be needed to ensure that costs comparisons are being made on a like for like basis.

7.4 Recently, Government has announced plans to tie payments more closely to quality outcomes11. It would be important to consider the impact of mobility on this initiative and ensure that commissioners have access to comparable information on quality and outcome measures, particularly patient satisfaction measures.

8.0 EU COOPERATION ON HEALTHCARE

8.1 The RCN supports moves to strengthen cooperation in the EU on health technology assessment and the continuing development of centres of reference/excellence.

8.2 The RCN also welcomes proposals for a system of mutual recognition of prescriptions which recognises the prescribing roles of a range of health professionals. In a number of member states12 nurses now have prescribing powers and any new e-prescription system needs to recognize this.

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10 Ibid
12 Includes UK, Ireland, Sweden, Spain, Netherlands
8.3 E-health interoperability, particularly in relation to patient records, will have a significant impact on ensuring safety and continuity of care from referral, to treatment, after care and recovery. This means focusing on safe communication to support safe care, rather than prioritizing data standards, as outlined in the RCN’s recent policy statement on electronic patient records.\textsuperscript{13}

8.4 Work to improve e-health interoperability will also need to address any language barriers to clinicians and patients accessing and communicating information relating to patient data as these will not be resolved solely through technical standards.

8.5 Finally, the proposed directive enshrines in EU law for the first time the overarching values (eg solidarity, universality, equity) and operating principles (quality, safety, patient involvement) for health services agreed by health ministers in 2006\textsuperscript{14}. It is unclear what this will mean for the long term in relation to future EU initiatives on health service provision or the potential challenges to national regulatory and standard setting systems at EU level, particularly within the European Court of Justice, which has played such a key role to date in clarifying patients’ rights in cross-border care.

\textit{September 2008}

\section*{Examination of Witnesses}

Witnesses: Ms Jo Webber, Deputy Director of Policy, NHS Confederation, Ms Susan Williams, Head of International Affairs and Mr Tim Curry, Policy Adviser, Royal College of Nursing, examined.

\textbf{Q242 Chairman:} Welcome. We are grateful to you for giving us your time this morning. Unfortunately the representative from the Royal College of General Practitioners is not able to be with us. She is sick, as we understand it, and therefore we just have two organisations this morning. If you find that at the end of the day there are things you have not been able to say that you would like to have said, you would be very welcome to send us supplementary evidence. We would be very grateful for that. We do see this as an extremely important inquiry. When we began, we knew there were complexities. As we go into it, we discover that the complexities are even greater than we might originally have anticipated. I think it is going to be quite useful for us to uncover that for the Government and then for the Commission itself when we finalise our report, so we are very grateful to you for coming. I would like the witnesses from the NHS Confederation, followed by the witnesses from the Royal College of Nursing, to start by stating your names and official titles for the record. Then, if you want to make a short opening statement you may, but we will continue with the questions. It is helpful if you do not answer the questions in a full opening statement, otherwise we find we have to follow-up in a different way. Would you begin by stating your names, please.

\textit{Ms Webber:} My name is Jo Webber. I am a policy adviser for the Royal College of Nursing. Good morning. My name is Tim Curry. I am Deputy Director of Policy at the NHS Confederation. We welcome the opportunity to go through the issues that we have already given you in our written evidence and also to tease out some of the issues that maybe did not come over in the written evidence but which will be of help to the Committee. We feel this is an intricate, complex issue, and it does take a lot of unpicking to see the real impacts of this on NHS organisations and on the NHS system—particularly in England. I have to say, quite a lot of our evidence is from our English members. Our members are the organisations that make up the NHS, that deliver NHS services, and that includes not-for-profit organisations, for-profit organisations, and NHS Trusts.

\textit{Mr Curry:} Good morning. My name is Tim Curry. I am a policy adviser for the Royal College of Nursing. My colleague Susan Williams will be making our opening statement.

\textit{Ms Williams:} I am Susan Williams and I am Head of International Affairs at the Royal College of Nursing. I wanted to make a few comments. First of all, I would like to say how pleased we are that you are looking at this particular issue because of its importance. Whilst the numbers of patients seeking cross-border care are very small, the proposed legislation has potentially some significant implications for the UK. As you have mentioned, this is a complex piece of legislation and we wanted to flag up initially some of the challenges in relation to this Directive. There is a tension between the objectives of the single European market for the free movement of individuals and services, which is the treaty base for this proposal, and the need for national health systems such as the NHS in the UK to plan a whole service within limited budgets and to ensure equity. There are tensions around the need to balance the rights of Member States to determine the organisation, financing, and delivery of health services in their country and the need for some assurances, particularly relating to safety, quality, and redress, if patients are being treated in another EU country to which they have a right. There are other tensions around the need to address the wider


\textsuperscript{14} Council of European Union, Council conclusions on common values and principles in EU health systems, 1–2 June 2006
policy and practical issues for patients in cross-border care, for the patients, the professionals, the providers and the regulators in fact, rather than policymaking being based solely on individual European Court of Justice rulings on individual patients' rights. Given that context, as a nursing organisation our key concern has been to focus on ensuring that the Directive provides the framework for a workable system for the small number of patients who do seek healthcare in another European country but not that this Directive should be a highly detailed piece of legislation, particularly given that health systems across Europe vary and that there is also a wide number of different types of cross-border care. We also want to ensure that any system does not undermine continuity of care and planning of services, particularly for the vast majority of patients who are also seeking care in their locality, and we want there to be clarity in the UK about the practical implications of the Directive here for patients and, of course, for those working in the Health Service.

Q243 Chairman: In your introduction you mentioned this issue about equity and this tension between the wider EU and individual services. We wanted to begin, as you know, by talking about equity. The RCN suggests that instead of a system whereby patients are required to pay upfront there should be direct transfer of payments between funders and that this should be made explicit in the proposal. Could you begin by expressing your views on the equity of the proposed Directive. How well do you think the proposal addresses issues of equity, including the requirement for a patient to pay upfront for their cross-border treatment?

Ms Webber: Obviously there are some barriers that are very clear for people with less money and less resources to pay upfront, and for those physically unable to travel, and for those with language barriers which mean that they do not understand the available options in quite the clarity they need to. We feel that there needs to be good access to information so that people have a range of approaches they can choose between and that the commissioners need to have the flexibility to meet upfront costs where that is necessary to enable choice. Although we are rather concerned that the direct transfer of funds could benefit the better-off, who would have more chance of being able to take up things, we do think there are ways in which the commissioners should be allowed the flexibility to enable people to have some of their costs paid upfront. There is obviously already the E112 system, which enables in exceptional circumstances for the costs to be paid, and we wonder whether this is something that could be built on, with more guidance for commissioners so they could use this more flexibly to enable the less well-off to pay upfront. But I think it needs to be remembered that the costs are not solely the costs of treatment: there are other costs, particularly travel costs, that need to be considered. We believe that the guidance on the travel costs scheme needs wider publicity so that people are quite clear about what they are entitled to for the other costs of the treatment.

Q244 Chairman: Just as they are with the E112.

Ms Webber: Yes, but the travel costs scheme.

Q245 Lord Wade of Chorlton: This is a matter that we have heard discussed previously. When I have listened to the evidence—and I am not an expert on these matters so I am just influenced by the evidence—there are clearly issues that could make it very difficult for patients, who may believe that it is an easy solution to be able to travel somewhere when in actual fact there are a lot of implications. The fact that a person is making a small payment upfront, whatever it may be, does enable them or encourage them to learn a little bit more about what might happen and the implications of doing it. Would you agree with that point?

Ms Webber: Absolutely. I think there is a core role to ensure that the patients are getting all the information they need to make the decisions about whether they take up cross-border care. That is one reason why we would come back to prior authorisation schemes, because we believe that one benefit of those is to sit down with the patient, the commissioner, and the clinician, to be able to go through what the real cost will be to the patient and what the cost will be to the system, what needs to be borne upfront and what can be claimed back later.

Q246 Chairman: Could I get that absolutely clear in relation to what Lord Wade is asking and the second point you have made. In terms of equity, the point you made at the beginning was that it is important that people who are better off should not have the advantage over people who are less well off. Lord Wade is saying that if you pay a bit, you think about it. You are saying that the better system would be prior authorisation. We will come to that later but I just want to be absolutely clear on your answer to Lord Wade.

Ms Webber: Our understanding is that prior authorisation would give that time and that space for people to have the discussion about how care is going to be funded and what the best options are for them. I think that might get us over some of the issues around that alongside the commissioners having more flexibility to look at how they could part-fund costs upfront for the less well-off.
Q247 Lord Wade of Chorlton: Would that authorisation, in your view, explain the disadvantages—the hazards, if you like—that might arise from this decision?

Ms Webber: We would want that information to be fair and to cover all the options, so that patients can make a really informed choice about what they are doing.

Q248 Chairman: We are going to probe that further in a little while. Could I just see whether the Royal College of Nursing has anything to add.

Ms Williams: In our evidence we linked the payment issue with prior authorisation. Our main concern was that certain socio-economic groups would be disadvantaged if there was an assumption that all costs would be paid upfront and reimbursed. The language of the Directive is “reimbursement”. Some of these costs, if they are hospital and highly specialist costs, will not be negligible and we are concerned about the fact that that might disadvantage particular groups. However, in our evidence we said that the option for transfer of payment should be given where patients have sought prior authorisation. Although that is an issue we are going to come to later, the two issues are intimately linked.

We are saying that there needs to be a discussion clearly with clinicians and with funders in the UK around what the options are and what the best treatments are, and that if those are things which are agreed prior to any treatment taking place, there is no reason why those payments should have to be made upfront. It should be possible to transfer those payments. As was mentioned before, there is a system in place already under the EU social security arrangements where there is prior authorisation and where those arrangements are made and patients are not expected to pay upfront.

Chairman: Indeed, it happens in other specialisms in other ways.

Q249 Lord Lea of Crondall: I would like to check that both Ms Webber and Ms Williams are talking totally symmetrically about UK citizens going that way and, say, Polish citizens coming this way, because all your remarks seem to me to be more addressing issues from an NHS perspective around people going that way. Do you think we ought to be talking to the Polish College of Nursing about people coming this way? Are you talking both ways?

Ms Webber: I think we probably are talking both ways, yes. To be clear, to get real equity we do need to enable this to work across the European Union. We would not be advocating that people who cannot afford to pay upfront should have no responsibility to pay upfront, but we are saying from an equity point of view that for the people who cannot afford it there should be some flexibility to enable them to move to receive the healthcare they want on the basis of the information they have been given. But I would have thought this was in both directions.

Ms Williams: We have been collaborating with our sister organisations across Europe for over 30 years now. Certainly within our European Federation of Nurses Associations, where all those organisations come together, this issue about payment upfront, particularly for expensive treatment, is a concern shared. We are looking also at equity as far as possible. UK citizens being treated in the UK are not normally expected to pay upfront for treatment that would be covered by the NHS, but there are other health systems in Europe where there are thresholds and where a patient in any case would pay small amounts upfront and then get it reimbursed by their insurance systems, so it would be up to those Member States to determine how this system fitted with the system that was in place already. We have to acknowledge that the health systems across Europe are not all the same and we have different levels of co-payment and other issues.

Q250 Chairman: Some of this does introduce many of the other areas we are going to talk about, but while we are in this area perhaps we could deal with this fraught issue of top-up which has had its own debate here in the UK, particularly in England, never mind in Europe. The RCN is particularly concerned and feels that top-up payments would create gross inequalities in care but has sympathy with some patients who may wish to top up. There is a double message you are giving us there and we need to clarify that. What do you think of the potential for patients to top up that is created by the proposed Directive? How do you think this should be addressed, particularly with regard to the principle of equity that we have just been discussing?

Mr Curry: Perhaps I could start by clarifying our position on top-up payments because it is not a straightforward situation for many people. If we start off from the principle of asking people to add money to improve either outcomes or the choice of treatments they have, that in itself creates inequity. We are fairly clear on that. Whether we are talking about cancer payments, which were the subject of Professor Richards’ review, or other forms of treatment, we are most keen to avoid a situation where some patients would have access to a business class service whilst the rest of us would be only able to have, say, standard traveller class, if you will. That was our starting point. Because of the way in which NHS guidance on private payments was constructed, where somebody brought in private funds, say, for a private prescription, particularly around things like cancer services, they lost entitlement to free NHS care with that. In a sense, it was not just that they had to pay, but that they would also lose an entitlement
The old guidance used to be constructed. We are concerned about the principle of top-ups. We believe that somebody should not be able to pay to get better care to disadvantage somebody else or to take the resources away from somebody else, but the current system makes it doubly difficult, in that if somebody did pay, they would lose what they should be entitled to under the NHS anyway. Our evidence to Professor Richards’ review was that, because of the situation where people in need were losing entitlement to care and having to mortgage their homes, do fund raisers, and so on, we felt that top-up payments should be allowed but only for a limited period, to allow a full risk assessment of the impact of allowing a broader system of top-up payments because we do not think that enough is understood about the implications of that. Secondly, the real problem for us lies not in the principle of top-up itself. The solution lies with primary care trusts. They have the responsibility for paying for drugs which are not yet authorised by bodies like NICE to be funded under the NHS. Our members have told us that they would be working in a cancer clinic and two people would come with the same condition from two different PCTs and yet be entitled to entirely different drugs. That is clearly a gross inequity and needs to be addressed. That seems to us to lie with primary care trusts, whose exception processes are variable: some are high quality and very robust and some are not so. In a nutshell—and it is a rather large nutshell—that is our position on top-ups. We were forced to say, “Let’s allow top-ups for now, do our homework, improve NICE processes, speed them up, improve PCT exception processes and the information around those, and engage clinicians more actively on this very thorny issue.” I think it is one for a public debate really about how we allow this to grow. We should not allow it to creep from one state to another without a public debate.

Q251 Chairman: I admire your optimism. I would like to probe just for a moment the issue about equity across PCTs and the difference between commissioners, because that is where the issues will also be developed. How do you think we are practically going to achieve that in the European Directive, bearing in mind the difficulties we have had coming out of postcode lotteries within the UK itself. I am sorry to ask you that, but I think it is worth following up.

Mr Curry: A small question! Rather than trying to prescribe a precise process for all bodies, we would be looking for some consistent principles to be applied. Without naming PCTs, some spoke to us, as it were, in confidence about the challenges they face, some PCTs had a very clear process of clinical engagement and public and patient engagement and invested heavily in that, some PCTs did not have similar resources or a similar approach and so there was a more bureaucratic process. The outcomes were different. Was that due to the process or was it due to allocation of resources to the primary care trust or to the effectiveness of the clinician advocating for that particular case? We do not know. These are all good questions. Out of those questions and a sensible inquiry could come some principles which all PCTs would have to reflect, and maybe change the way they did things but at least address the principles and demonstrate they were trying to do that. On the subject of postcode lottery, it would seem sensible to us that if a commissioner is faced with a higher need for services to tackle obesity than another, then they should spend more on tackling obesity. Variation in provision is not necessarily a bad thing. It is the evidence on which that is done that is important and the ability of patients to see why things are different and to be part of that decision-making process. To go to a European level again with that, we are not looking for detail in the Directive. We are not looking for prescriptive policies and procedures and hurdles, but we are looking for some principles about equity that clearly instruct Member States about how they can best create the framework so that people receive the right information and are very clear about the impact of taking one model of care over another, particularly when it comes to top-ups. As we said in our evidence, it is not just about the care, but it is about the transport, it is about the follow-up care. Follow-up care can be just as expensive as the original treatment.

Q252 Chairman: Do you have any different points on that, Ms Webber?

Ms Webber: We would agree that the way in which exception panels work within PCTs needs to be revised, so that there is more consistency across the piece, so that those decisions and the way in which those decisions are reached is clear and transparent to people. We would also say, though, that one of the Richards review principles on which this was based was that there should be no detriment to other patients’ entitlement to NHS treatment. Whatever was done at the European level, we would not want this to enable somebody to get more or less than their entitlement on NHS treatment.

Chairman: Thank you very much indeed. It all moves on to information and how people know about it.

Q253 Lord Eames: I think we are all agreed—you have already mentioned this on several occasions—on the importance of information, but we would look to probe whose responsibility you think it is to provide that information. What do you think the information needs to contain? What are the parameters for that? What is your view on the need to
consider and address the information requirements of health professionals in addition to patients, because we see the importance of both. It is really information I am after.

Ms Webber: We believe that the information needs to be about supporting choice. It needs to give patients all the different options so that they can assess what would be the best choice for them and what the best health outcomes would be from the different options. Having said that, we think there is a real issue around ensuring that local PCTs and local clinicians and commissioners do have that range of information so they can support the patient in making their choice.

One thing we suggested in our evidence was that maybe there should be a network of national contact points, where information about the various ways in which the systems work might be useful, so that people have a point at which they can get more information about different national systems, but obviously we feel that the personal advice and advocacy is still the role of the local GP as the gatekeeper for a lot of care, the commissioner and the individual patient. I know we are going to move on to prior authorisation, but we do think that having that period during which you can assess what the issues are and what the various costs might be to you, and to be able to do that in a supportive way, is absolutely vital, so that people can make that good, informed choice. We do also feel that it may need guidance and capacity building, because we do not think that local PCTs would necessarily know the ins and outs of the healthcare system in, say, Poland or Hungary, and you would need to ensure that nationally there was some support for PCTs to enable them to have the right information for the patient to access.

Q254 Lord Eames: Whose responsibility should that be? That is what is important.

Ms Webber: I think we would say that it is the responsibility of the healthcare system. Particularly if we had a series of national contact points across the EU, that would be very helpful and it would obviously make sense for—

Chairman: We have had great difficulty in getting any witnesses to say who in the Health Service or anywhere else. Lord Eames is really trying to press you to say—

Lord Eames: As gently as I can, it should be said.

Chairman: You may wish not to answer the question or say it is difficult, but we are asking you the question.

Q255 Lord Eames: Can you help me?

Ms Webber: I am glad I am not the only person who has found this a difficult question. Obviously from our members’ point of view we would not want costly, bureaucratic burdens on PCTs. It would make sense to have one system nationally, rather than a series of local systems which meant that information had the capacity to get very muddled and mixed depending on where you were. Some of the issues we have previously talked about in terms of equity I think mean that this would have to be one central national system. Where that sits is probably still open for debate. I am not trying to fudge it, I really think there are various options.

Lord Eames: You see that is part of our problem and that is really why I am probing.

Q256 Chairman: We can have a view but we have to get our witnesses to tell us. I do not know whether the Royal College of Nursing want to add anything.

Mr Curry: I would like to add layers to the very comprehensive answer given by Jo. I think there are three levels of responsibility that need to be addressed—and this would be across the European Union. Practitioners who generate and collect the data have a clear responsibility to do so in a consistent way or a way which meets best standards, and there are standards internationally for information and data gathering and so on. There is a challenge there to equip and empower practitioners to gather information, particularly patient-centred information, which I think will be very important. Secondly, providers and commissioners, or whoever is involved in buying and selling and designing the care, have a responsibility again for collecting information but also for presenting it in an accessible way to whichever mechanism hosts this information. Finally, Member States have a responsibility for hosting that information in a way which is consistent in principle across the European Union. The European Union would have, again, a principled role to say the sort of issues that need to be addressed in presenting the information. Member States would have the responsibility for presenting that information in the most accessible way, bearing in mind the different needs and levels of education and access that people have to information generally—the use of public libraries, the internet, leaflets and brochures. Underpinning all of that there would have to be some very comprehensive communication and training and development for people on the frontline. The Confederation are quite right about the role of the GP but, also, of course, the practice nurse is increasingly seeing more and more routine referrals and is increasingly involved in choice. Nurses in that situation would need some very clear guidance about the extent of their role as advocates of choice without making too many very clear recommendations and pushing people one way or the other. You have a layer of responsibilities, therefore, which I think is nicely capped by the Member State presenting that information in a way that is accessible.
Q257 Lord Eames: Without some sort of protection, a nurse in that situation is going to be extremely vulnerable.  
Mr Curry: Nurses do this all the time. They frequently take complex information and re-present it to patients to enable them to make choices, and not just about formal consent for treatment but consent for different pathways.  
Chairman: Perhaps we could move on, because we are running very short of time, to Lord Wade and the co-operation between Member States.

Q258 Lord Eames: The very fact that they are giving that information, obviously in a subjective sense they will be thinking it through for themselves, means they are very vulnerable.  
Mr Curry: We have a system of regulation which gives us—

Q259 Lord Eames: Thank you.  
Mr Curry: May I quickly address information for health professionals as well, because I think that is a very important part of the jigsaw puzzle? There are two issues for us. Patient information, which needs to be transferred between providers and commissioners across borders and needs to be done safely, completely, and securely, is essential for continuity of care, obviously, and to make sure the patient information on treatment follows the patient. Secondly, there is activity and outcome information which will be useful for commissioners, particularly in a cross-border situation, to make sure they are getting value for money and that outcomes are comparable and useful for the person concerned.

Q260 Lord Lea of Crondall: Obviously one of the emotive questions to do with the private versus public is queue jumping. How do you get information across that you have spare capacity, that you can take a patient at that point in time? Or do you take the patient who is at the top of the queue? How does all that work?  
Mr Curry: Slowly. It is genuinely difficult. There is an issue of capacity within the NHS. Many Trusts are operating at high levels of capacity that the private sector simply would not operate at because they operate in that kind of market where they need to have flexibility to meet consumer need. The NHS is already working at 90% to 95% capacity in many cases. How do you achieve it?  
Lord Lea of Crondall: In this cross-border context.  
Chairman: I think we had better move back into the European context.

Q261 Lord Lea of Crondall: No, I mentioned it in the European context.  
Mr Curry: If you look at the different healthcare systems, some which are very much driven by an insurance system where that kind of information is routinely gathered and used, that might be very simple for some countries to do because they do that anyway as part of their system for delivering care. In this country, I would suggest, it would be slightly harder, but it is something that I do believe is getting better because of the way that information is now flowing throughout the system.  

Ms Jo Webber, Ms Susan Williams and Mr Tim Curry
be an awful lot more work done in terms of collaboration across countries on quality and quality indicators. That is at a very, very early stage, and there are very, very many different systems. Again, we would not necessarily be promoting them as one-size-fits-all, but we need to accept that there is a lot more work that can be done, and, rather than that being dictated in a Directive, that is something where organisations should be encouraged to collaborate. I will hand over to Tim because we think the e-health issues are particularly significant.

**Mr Curry:** I will try to be brief on this because e-health covers a range of issues, telemedicine, telecare, electronic prescriptions, electronic patient records, and that in itself is worthy of a few days’ discussion. Across a European level again, we come back to the point about interoperability, that co-operation between the industry, between providers, between Member States and commissioners, will need to be really improved. Although there is already some, it needs to be improved. Making systems talk to each other, even within NHS England, has proven to be a challenge, if I might be so polite, and there will be even more significant challenges going across borders if you add to that language barriers, differential diagnoses, and different terminologies. The Royal College of Nursing released a leaflet, a very short affair, a few months back, called *Make IT Safe*, and there are four broad principles that we think all systems should adhere to. The first is that the systems should have within them standardised terminology. There are international standards for health, things like SNOMED CT and so on. The platform and the product itself should be acceptable to clinicians and to the public. It should be useful, not an added burden. The technology needs to be fit for purpose. It needs to be robust and not breakdown and be able to be portable and taken around. Of course it needs to be evidence-based. We need to develop systems which are based on the best evidence we have. In terms of co-operation across borders, it is absolutely essential that we learn from the best and offer that across borders, to encourage the development of good systems which can talk to each other because, at the end of the day, e-health is about improving patient safety and the quality of patient care.

**Chairman:** We would value you sending us a few of those leaflets, if you are able to.

**Q264 Chairman:** They are taking the best.

**Ms Williams:** Yes.

**Chairman:** We need to move on to this vexed question of prior authorisation and Lady Neuberger is going to probe that in a little more detail.

**Q265 Baroness Neuberger:** I need to declare an interest as well, because I am a non-Executive Director of the Voluntary Health Insurance system in Ireland, which is a semi-state insurer, and obviously people come the other way, from Ireland to here, which is part of this issue. You have already said something about prior authorisation, and I suppose I would like both organisations to say what their basic view is about that, but I particularly want to pick up on the NHS Confederation’s view that a recommendation should be made that all patients seeking care abroad should be subject to a prior authorisation procedure. I think that is quite interesting, particularly if it is not people who are going to be paid for by the NHS. Perhaps you could have a general canter around it and then I will pick up little bits.

**Ms Webber:** As you quite rightly have said, we strongly support prior authorisation, not because this is a way of rationing the care but because this does enable people to make informed choices and it does enable people also to go into some of the quality and safety issues that have also been raised by my colleagues at the table with me. We also feel that it enables people’s expectations to be realistic about what they are going to receive or not receive, and it also enables people to understand the long-term implications, particularly issues like complications arising or where treatment is—
Q266 Baroness Neuberger: Aftercare?
Ms Webber: Aftercare as well.

Q267 Baroness Neuberger: Could I pick you up about realistic expectations. Do you really think there is any difference between the realistic expectations of care abroad rather than care here?
Ms Webber: I think it has the potential to be different, because people do look at those other systems based on public information about things and think that things are going to be better elsewhere. For instance, they think that somehow MRSA is entirely an English problem and the quality is going to be better elsewhere. I think there are some expectations that do need to be met. We find the distinction between hospital and non-hospital care quite false. We believe that if you are going to have prior authorisation and an enabling of choice then that needs to be for care whether it is delivered in hospital or out of hospital.

Q268 Baroness Neuberger: It simply does not make sense, because there is such variation across Europe as to what is done where.
Ms Webber: Absolutely.

Q269 Baroness Neuberger: Presumably you would say that not only is it a false distinction, but it does not tell you anything about how the systems operate in different countries.
Ms Webber: The issue is that you can have some quite complex treatments delivered out of hospital and quite safely out of hospital.

Q270 Baroness Neuberger: In polyclinics.
Ms Webber: Prior authorisation just being part of hospital care does not seem a sensible way for us. We do believe also that Member States need to decide for themselves really the circumstances for those systems. We do not think that the idea of prior authorisation just being there in exceptional cases meets the needs of individual patients or the systems. We also would say that the rules need to be set out nationally, so that people understand and have some transparency of the process which they are going to go through if they choose to have their care in another EU country.

Q271 Baroness Neuberger: Who would you expect to organise the rules of prior authorisation? Would you expect that to be the Department of Health?
Mr Curry: I think that needs to be done on a national level.
Ms Williams: Our view is largely similar. There are potentially constraints around European Court of Justice rulings, so there is a question about what should happen but there is also an issue about what can happen and what has already been ruled in law. There is question of interpreting those European Court of Justice rulings. The Commission has made an assumption that those Court of Justice rulings are saying that you are not required to have prior authorisation for non-hospital care, so there may be some work that needs to be done on how much leeway there is on that. That is why we have looked more at incentivising prior authorisation. That is particularly with hospital care, but, as we have said, the distinction between what is provided in a hospital and what is provided in another setting is shifting all the time. It is not even a static position, as care changes. We should be looking at encouraging patients to seek prior authorisation for all the other reasons we have mentioned, which is that there is then an opportunity for them not to have to pay upfront, they can discuss issues around continuity of care, et cetera, but it may not be possible to require prior authorisation in all circumstances. I can imagine that if somebody is accessing primary care because they happen to be abroad for two or three months, and there are small payments for that and they do not see it as practicable to come back to the UK or back to their country to seek prior authorisation, from a pragmatic point of view there seems little point in requiring it for those types of treatments.

Q272 Baroness Neuberger: Perhaps I could just pick that up, because I think this is where it is going to be key. You are going to have people living abroad or being abroad for three months, say—and that is common. They are going to be treated in a polyclinic, say in Italy, where they are all over the place, which is not defined at the moment as a hospital. You would say that pragmatically there is not a lot you can do about that, and in a sense you probably cannot have prior authorisation. What would the Confederation’s view be on that?
Ms Webber: I think you have to have some pragmatism about this. There are some things that potentially you would get, through maybe using your EHIC when you are on holiday, for which you would not expect to have prior authorisation, but in the main, as standard procedure, we would suggest prior authorisation.

Q273 Baroness Neuberger: For somebody who is going from A to B, as opposed to somebody who happens to be there.
Ms Webber: Yes.
Chairman: Lord Lea, you wanted to pursue this issue about liaison between service providers across the EU.
Lord Lea of Crondall: Yes, I was very interested in Ms Williams referring to 30 years’ experience in talking to other colleagues in Brussels and so on. I remember about 35 years ago, as a TUC official, that the RCN asked for some advice and whether we could show
them around Brussels, which we did. Anyway, I do not know whether both of you would like to say what the setup in Brussels that you work within is. Secondly, in that collective body you may have agreements and disagreements. Can you tell me, are there any different points of emphasis on this? Finally—if I may trespass slightly, Chairman—I still do not understand how information is agreed on whether a bed is available—say the four months waiting for a kidney transplant here or something which we have been through in another context. Are people supposed to have beds available as a priority if it is from somebody else? How do you discuss that? I am sorry, that is a slight trespass, but it gives an illustration of what you might call—

Q274 Chairman: Can I ask you to concentrate first of all on the question about liaison. We may come back at the end to some of the other issues. 

Ms Williams: The Royal College of Nursing is a member of several European networks but the two key ones are the one I have mentioned, the European Federation of Nurses Associations, which brings together professional and trade union nursing bodies, and also the European Federation of Public Service Unions, which is a wider collaboration of public sector trade unions, not only in health but in other areas as well. Within the discussions—because obviously there is a lot of debate going on in Brussels about this, and both of those organisations have permanent bases in Brussels with whom we liaise regularly—the key areas which we have highlighted, which are also areas that they have highlighted, are those around equity, so there are concerns about equity between socio-economic groups and the issue about upfront payments. The other one is around the importance of ensuring continuity of care and quality and safety frameworks, so not necessarily the detail of quality and safety but the need to ensure that those frameworks are in place. We should also say that there are other proposals coming out of the European Commission around patient safety and infection control, so there is a wider package of measures. One of the things that both of those European alliances have highlighted, which has not been a particular focus for us and which is also what they would see as the challenge, is the fact that they see this Directive as largely offering cross-border care more to the North and West European countries. For those in the South and Central and Eastern Europe, the costs that they would either be reimbursed or paid upfront, because healthcare costs are lower in their countries, would not cover a large amount of the treatment in North and West Europe. Our European bodies are also flagging up an inequity at that level. The other one to say about our trade union colleagues—and again that is an issue of emphasis because it is a much broader concern that they have overall—is the concern about internal market and competition policy in the European Union and the way that may impinge on public services and public service delivery in Member States. They have for a long time had a separate campaign to have a framework Directive relating to public services, so I think they would see this Directive as one element of potentially promoting internal market and free movement and competition rather than the provision of public services that are equitable for all.

Q275 Chairman: Lord Lea, I am going to hold your other question for a moment—I know you have asked it and it is an important question—because we are running short of time. We can always do with more time when we have witnesses who are giving us good information. I am sorry, Ms Webber, is there something else you want to say?

Ms Webber: Yes, in terms of our liaison with other EU bodies, we host the NHS European Office, which is based in Brussels and funded through the strategic health authorities. This office is the only one we know of in Brussels that represents a whole health system. It obviously gives us quite a high level of access to policymakers and we engage directly with the Commission and with European Parliament Members but we also work with relevant representative bodies, including HOPE, the European Hospital and Healthcare Federation, which has members from 32 organisations, representing 26 different EU countries and Switzerland, and obviously liaises between different healthcare systems. We do know that our views are aligned with HOPE’s views in terms of the issues around prior authorisation and that HOPE has a position paper which is available on their website outlining their position on this. We also work with EHMA, the European Health Management Association, and through NHS Employers with an organisation called HOSPEEM, the Hospital and Healthcare Employers Association. Again that enables us to gauge what the views are across other Member States. Our feeling is that there are some common issues around patient information and the impact on equity that will be picked up by those organisations.

Q276 Lord Eames: We have been talking about cross-borders and what-have-you. Now let us look at the UK. Devolution has caused as many problems as it has solved. I should declare an interest on this! It may be obvious.

Ms Williams: In terms of our response and what we feel is appropriate from a European Directive, the main issue for us has been that as long as there are transparent systems in place about what healthcare is available in any one of the four countries and what would normally be covered for funding, and as long
as those systems are transparent and accountable, then we would want to ensure that any Directive at EU level does not take away the rights of the four countries to determine how they are going to prioritise health and that there will be differences.

Mr Curry: Could I make a very quick illustration of some of the challenges in devolution around how care is funded for within the NHS. In England we have a system called Payment by Results, a system of paying for activity really, and that has been constructed quite uniquely in NHS England. The other three countries do not use a system like that, although Northern Ireland is piloting similar approaches. We are left, therefore, with confusions about how reference costs are created or how prices are made. That has been manifest in cross-border care between England and Wales, between specialist children’s services in the Welsh borders, and between Scotland and England, and between Northern Ireland and Southern Ireland as well. So, although the case-mix payment systems are common through many parts of the world, even within the UK there are substantial differences of interpretation about what is a cost and what is not a cost, what is a diagnosis and what is not, who is involved in that process and how transparent it is, and so on and so forth. Devolution has provided some difficulties there but they are not insurmountable.

Ms Webber: We would absolutely agree that in terms of the framework the Directive needs to provide a framework but it would still be down to the local health systems. There are issues of difference between the four health systems within the devolved administrations and England. We would not want for an European Directive to make that situation more complicated than it is at the present time. Obviously the more guidance you have, the more room there is for some of those complications to take hold.

Q277 Lord Eames: Whose responsibility do you think it should be to try to tackle some of these things? Are they more piecemeal or is there any attempt to wave a stick at everybody and say, “For goodness’ sake solve these problems”?

Ms Webber: Between the European system?

Q278 Lord Eames: Within the UK devolved situation.

Ms Webber: I think with devolved administrations we are always going to get differences in approach towards things. The real point is to make sure that where people live at the edge of one system, in particular, they do not get disadvantaged.

Q279 Lord Eames: This is the point.

Ms Webber: There has already been a lot of work between the English and the Welsh systems and I think that is where we should continue.

Chairman: We are through the hour, but if you are happy to continue, although we will lose one or two Members because they will have to go to the next session, we would like to continue for a few minutes.

Q280 Baroness Perry of Southwark: I suppose at the heart of all the questions we have been asking is the issue of how we can ensure quality of care for patients if they do cross borders for their care. My question relates, first of all, to what the Royal College of Nursing said in their written evidence, that you thought the responsibility for ensuring quality should be in the Member State of treatment and not the home country. Could you expand on that. We hear what you believe is necessary in the light of the complex pathways of care that may arise and how we can guarantee the quality. Are there any lessons that we can learn from the London Patient Choice project, covering patients who were sent to five hospitals in Belgium in 2003-04?

Ms Williams: In terms of what we want to see in the overarching Directive, the reason it is important to clarify who is responsible for safety, quality, and redress—that is, the country of treatment—is that we have had previous proposals from the EU, notably the Services Directive, where the opposite proposals were given, particularly with the free movement of services, where a service provider would be able to set up in a country and not be necessarily subject to the quality and safety regime of that country. It is quite important, therefore, that if somebody is being treated in the UK they should expect to be treated under the regulatory frameworks that operate within that country, and, equally, if somebody is being treated in another country, under that regulatory framework. From the practical point of view, there may well be issues—and we have talked about this already—about the kinds of discussions that an individual patient may have before they leave their own country and discussions around continuity of care, but, in terms of the framework, it is important that if you are being provided care in a particular country where, for example, those health professionals are registered and where those providers operate, that you should be subject to the regime in that country. In terms of the London Patient Choice Project, we flagged that up because it was part of a very useful wider study that has been done about cross-border care and quality. There is generally very little evidence around, which is why it is such a welcome piece of work. The London Patient Choice Project may have some lessons for us, however it was a very specific pilot. It had funding put into it so that things like travel costs were covered. It had a lot of intense work done on patient liaison and information so that patients making choices either to go elsewhere in the UK or to go abroad had an awful lot of information available to
them—quite a tailored service. I think the other issue to raise is that quite detailed contracts were agreed which would be unrealistic in the context that we are talking about, unless we are again expecting there to be commissioning of care abroad in a cross-border context. It was also done at a time when there were very long waiting lists, so that was one of the reasons for it being set up. Realistically, the parameters are unlikely to be the same. However, it did flag up issues about the fact that patients did find having that information very useful and that they would have wanted to be more aware of the wider costs associated with treatment abroad—so the psychological costs or the costs for relatives, et cetera, if they were seeking a treatment where they would want to be accompanied. It also flagged up the fact that they had mixed experiences of referral from the UK and aftercare when they returned. That is partly why we also flagged up the issue of information and education of health professionals.

Q281 Baroness Perry of Southwark: Is there not a slight contradiction, that you understandably emphasise the need for information and the information to be given in this country? Let us talk about people going from here into another country. If I get what I think is good advice from my GP, via the centre of information or whatever, that I can have an absolutely super operation in Northern Italy or somewhere, and I go there and it is a disaster, am I not going to be just as likely to feel I have been cheated by the information givers in my own country as by the treatment givers in the other country?
Ms Webber: I think you probably are in that situation. Part of the reason for going with prior authorisation is the ability to have that time period when you can have a very fair, honest, and open discussion about what the issues are. The other thing to note which probably did not come across was that the London Patient Choice Project was a contracted thing, contracts were laid. In terms of somebody seeking cross-border care, the contract is between the patient and the provider, and that means that the
patient, if you like, has the onus on them to have gone into the issues around quality and safety for the provider that they are going to elsewhere. This is where I think getting the information right and giving people a really clear understanding of what the issues are is important, because some of the quality standards that we have are going to be different in different countries and in different systems. One way that could be overcome would be for European providers to sign up, to almost have the NHS terms and conditions placed on our choice menu, but there is an issue about liability for care delivered under another regulatory system in a different system. We are not clear what the legal implications of that would be, but there is a very great difference between the contractual thing that went on within the London Patient Choice and what we are dealing with here, which is individual contracts.

Chairman: We do have to finish there, which is a great pity, because had there been time I would have asked you the question that swept up Lord Wade and Lord Lea’s point in terms of proportionality, we know we have to do something because of the Watts European Union finding. In terms of proportionality and understanding different systems, having enough information to answer Lord Lea’s question which is how do you know where anything is, getting commissioners to have that information, seems to us a huge task. We are really asking if you agree that although this has to be tackled it could quite overwhelm resources in relation to the size of the issue that it is dealing with. I think that is what Lord Wade was asking right at the beginning and Lord Lea is trying to get at by asking you specific questions. You are nodding.

Lord Lea of Crondall: If we could have a supplementary note on that, I would be grateful.
Chairman: We would be very grateful to have a note on that because it is what is beginning to concern the Committee, I think, that things have to happen but the size of the bureaucracy could be greater than the answer to the question. Thank you very much. As you can see, the Committee have valued your evidence greatly and we are sorry we have run over.

Supplementary memorandum by the NHS Confederation

1. Jo Webber, the NHS Confederation’s Deputy Director of Policy, gave oral evidence on 4 December as part of the Committee’s inquiry into the European Commission’s proposals on cross-border healthcare.

2. The Committee requested a supplementary written note on the challenge of understanding the different systems in place across the EU and obtaining practical information on cross-border healthcare options, whilst ensuring that systems to support cross-border healthcare remain proportionate to the level of cross-border activity.

3. The NHS Confederation recognises that this is a considerable challenge. The draft directive includes proposals for a network of national contact points on cross-border healthcare, which, it is envisaged, would be responsible for collating and exchanging information about cross-border healthcare in each EU member state.
4. As we said in our evidence, we think these national contact points may be helpful in terms of providing general information about rights to cross-border healthcare and how other member states’ systems function, but we do not think they will be able to provide personal advice on the best care or act as advocates for individual patients.

5. Most patients will look to their local NHS, often their own clinician, to help them make decisions about their healthcare. However, responses to the NHS European Office’s recent consultation on the proposals suggested that, with a few exceptions, awareness of rights to cross-border healthcare is very limited at local levels of the NHS. In view of this, we think there will be a need for capacity building and support in this area as part of implementation of any future directive.

6. We also think it is important to be realistic about the level of information on cross-border healthcare that health professionals and staff in local NHS organisations will be able to give. It may be that in many cases, they would discuss a patient’s individual needs and entitlements with them, and then signpost them to other sources for more general information, eg on standards of quality and safety that would apply in the country where they were interested in receiving treatment.

7. In our evidence, we explained that we strongly support the use of prior authorisation systems as a mechanism to provide information to patients interested in cross-border healthcare to help them make an informed choice. It is unlikely that the NHS would ever be able to provide the same level of information about cross-border healthcare options as it could about options within the NHS. However, prior authorisation systems do offer an opportunity to make patients aware of important factors to be considered in a decision to seek cross-border healthcare, for example, the fact that standards of quality and safety and clinical practices may be different in other member states.

8. There may be merit in developing materials to support patients considering cross-border healthcare options, such as sets of questions they could ask a prospective healthcare provider. Involving public and patients in the development of guidance and information on cross-border healthcare would be helpful in trying to dispel misconceptions and misunderstandings about what exactly patients are entitled to.

9. We also think that, in the interests of equity, consideration will need to be given to the provision of information in accessible formats and potential extra help or support for vulnerable patients or those with complex needs. This may be an area where approaches that share resources or pool expertise could be useful.

10. We think the NHS has a responsibility to ensure that patients can access information about their healthcare options, including cross-border healthcare, easily and in a format that is clear and understandable to them. Where patients are interested in cross-border healthcare, the NHS should provide clear information on eligibility requirements, level of reimbursements and processes for obtaining prior authorisation, where this is required.

11. However, it would be neither proportionate nor equitable for the NHS to devote unlimited resources trying to provide the same level of information about cross-border healthcare options as about options within the NHS. We do not, for example, think it would be the role of the NHS, in the majority of cases, to try to obtain information about whether a particular specialist or centre in another EU country has capacity to treat an individual patient who is interested in travelling there for treatment.

12. We consider that, where the NHS can provide treatment in a timely manner in the UK and patients are deciding for personal reasons to seek treatment in another EU country, in choosing to obtain care outside the NHS, patients take on an additional degree of personal responsibility for their choices. We think, for example, that patients should be responsible for finding and choosing their own healthcare provider.

13. Nevertheless, we think that a number of actions, such as the development of materials as mentioned above, could be taken to support patients in making informed choices about cross-border healthcare. We think that these actions, though requiring some additional resource, may well prove cost effective in reducing the risk of complications arising from poor quality or inappropriate healthcare received in another country.

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15 The NHS European Office is part of the NHS Confederation and is funded by the Strategic Health Authorities. It was set up in September 2007 to inform NHS organisations of key EU developments and to promote the priorities and interests of the NHS to the European Institutions.
NHS EUROPEAN OFFICE CONSULTATION ON THE EUROPEAN COMMISSION’S PROPOSALS FOR A DIRECTIVE ON THE APPLICATION OF PATIENTS’ RIGHTS IN CROSS-BORDER HEALTHCARE: SUMMARY OF RESPONSES

Key Points Emerging from the Consultation

Responses to the consultation came from a diverse range of NHS organisations and many different opinions and points of view were represented. However, some common themes emerged strongly from the consultation. These can be summarised as follows:

— We do not expect a large increase in the volume of cross-border healthcare as a result of the framework set out in the draft directive. Systems established to provide for and facilitate cross-border healthcare should be proportionate to the level of cross-border activity and should respect the organisation and structure of health systems.

— Where a patient makes an informed choice that they wish to receive planned healthcare in another EU country, they should be supported to do so. As well as looking to remove unjustified barriers to accessing cross-border healthcare, the legislative framework put in place should consider mechanisms to support informed decision-making.

— It is crucial to recognise that, within many systems, decisions about what treatment an individual can receive are made at regional and/or local levels. Such decision-making processes must be allowed to continue.

— Prior authorisation systems should not be seen as a barrier to accessing cross-border healthcare. They offer a valuable opportunity to ensure patients have the information they need to make informed choices about cross-border healthcare. They are also an important aid to help healthcare systems plan services and manage financial resources to the benefit of all patients.

— The provision of information is absolutely fundamental to supporting patients who are interested in accessing cross-border healthcare. It is important to recognise that patients will need a range of information from different sources to make an informed choice about the best healthcare options for them.

— Information on quality and safety systems as well as differences in clinical practices and the way healthcare is organised and delivered in other EU countries will be a key element of patient information. However, these matters are the responsibility of the appropriate national authorities and the legal framework should not interfere in how they are managed within member states.

— There is significant and widespread confusion and misconceptions throughout the NHS about the current rules on cross-border healthcare, existing arrangements under social security provisions and what changes EU proposals in this area may lead to. There were strong calls for clear guidance on the different routes to accessing healthcare abroad and their application in the context of the NHS.

— Some NHS organisations expressed an interest in developing opportunities to offer more cross-border healthcare. There were calls for guidance clarifying what scope NHS organisations have to pursue such opportunities.

— There were concerns that requirements in relation to data collection on cross-border healthcare should not be too complex or burdensome and should not result in resources being diverted from patient care.

— There was interest and support for cooperation with healthcare systems and providers in other EU countries, particularly from providers of highly specialised services. It is important that current initiatives are taken into account and that flexibility is maintained in the scope and direction of future developments.

Introduction

In the past, the NHS did not provide reimbursements for healthcare received in other EU countries. As the vast majority of NHS healthcare is provided free at the point of use, the NHS had no systems for calculating levels of reimbursements due if healthcare were paid for upfront. In addition, the NHS has no defined list of healthcare for which all patients are eligible. The treatment that a patient can receive is determined at a local level, based on an assessment of their individual circumstances balanced against the healthcare needs and
priorities of the wider local population. As a result of these and other factors, implementing rights to cross-border healthcare raises some significant challenges for the NHS.

In July 2008, the European Commission published proposals for a directive on the application of patients’ rights in cross-border healthcare. The aim of the proposals is two-fold: to clarify the rules associated with the right to access cross-border healthcare; and to put in place measures to support the provision of cross-border healthcare.

The right to access cross-border healthcare in certain circumstances has been established by the European Court of Justice, and cannot be removed. However, the detailed framework set out in the draft directive could make a big difference in terms of how complex and potentially burdensome implementation is, in practice, for the NHS and how clear and easy the system is for patients to use.

In view of this, NHS European Office undertook a major consultation process focussing on the potential implications for the NHS of the proposals set out in the draft directive. In particular, the consultation aimed to explore aspects of the current proposals which might be particularly problematic for the NHS, or where changes to the proposals could potentially make the framework clearer, easier to implement, or less burdensome to the NHS.

The consultation process

The NHS European Office prepared a consultation document which was circulated to NHS organisations, and published on the internet. A number of specific consultation meetings were organised and the issue also raised and discussed at a range of other meetings, conferences and events. Discussions were also held with a range of other stakeholders from the UK healthcare community. The consultation ran for a period of three months. The consultation document can be viewed via the NHS European Office website at:

www.nhsconfed.org/europe

SUMMARY OF RESPONSES TO THE CONSULTATION

Cross-border healthcare: potential impact on the NHS

From a UK perspective, travelling to another EU country for healthcare is likely to be associated with additional costs and inconvenience as well as possible language barriers, when compared to obtaining treatment at home. Bearing this in mind, contributors did not anticipate a large expansion in the volume of cross-border healthcare, either to or from the UK, within the framework of the draft directive, provided that patients understood that they did not gain any rights to receive reimbursements for treatments that would not have been funded at home.

In view of this, contributors felt that systems established to provide for and facilitate cross-border healthcare should not be disproportionate in scale and cost to the level of cross-border activity and should not have wider, unintended, consequences for health systems as a whole. Contributors did not believe that the promotion of cross-border healthcare should be an objective in itself. Rather, the objective should be to provide clarity about the rules relating to cross-border healthcare so that interested patients are able to make informed decisions within a framework that respects the organisation and structures of different health systems.

Some NHS organisations, for example, centres of very highly specialised care, have long experience of providing healthcare to patients from other countries. Other NHS organisations have had to respond to a changing local population as a result of recent migration patterns. Compared to these wider phenomena, contributors did not think that incoming patient flows as a result of cross-border healthcare provisions would, in general, have a significant impact on NHS provider organisations.

Nevertheless, there could be an impact on a small number of highly specialised services, where expertise and/or capacity are limited, and some contributors felt that, in some circumstances, there could be a need to give UK-resident patients higher priority than incoming patients from other countries. Examples cited included when dealing with organs for transplantation that are in short supply and when supplying a very highly specialised service, of which there may be no other or a very small number of EU providers, and the number of incoming patients risked jeopardising the NHS’ ability to meet relevant standards for domestic patients, such as the 18 week waiting standard. However, these were very much exceptional examples, and for the vast majority of services, contributors felt that incoming patients would be accommodated and treated on an equal basis to local patients.
Some NHS providers said they would be interested in exploring opportunities to provide more services to EU patients, in particular in areas of specialist expertise. In such cases, extra capacity would be planned so that additional patients could be treated to the benefit of, and not the detriment of, NHS patients. In order to facilitate this, NHS providers would welcome clarification on the rules which apply to patients coming from other countries and what scope NHS organisations have to pursue such opportunities.

Turning to outgoing patient flows, whilst, overall, contributors thought that relatively few NHS patients would seek treatment abroad, it was noted that there may be some circumstances in which greater numbers of patients could choose to obtain cross-border healthcare. Some examples might include:

- Individuals with personal links in other EU member states who prefer to receive healthcare in the system they know best.
- Individuals who regularly spend extended periods of time in another EU country (eg retirees who spend three to six months of each year in the Mediterranean region) for whom it is convenient to receive healthcare in that other country.
- If capacity limitations or the lack of a nearby provider for a type of healthcare means that it is easier for patients to travel abroad to access healthcare.
- If a patient wished to receive treatment from a specific specialist or facility because they perceived they could benefit from their particular expertise.

Contributors recognised that patients in circumstances such as those illustrated in these examples may benefit from receiving treatment in another EU member state. There was a strong view that where patients had made an informed choice to seek treatment abroad they should be supported to do so. In order to facilitate this, there was overwhelming support in favour of a system providing for patients and their commissioner/insurer to discuss arrangements before treatment is obtained abroad as the best way of doing this.

Patients would, in any case, need to contact their commissioner/insurer to obtain personalised information regarding eligibility requirements, level of reimbursements and processes for obtaining prior authorisation, where this is required. Therefore such an approach would not constitute an undue barrier to cross-border healthcare and should reduce risks for both parties at later stages, eg disputes over reimbursements or whether a treatment was necessary.

In the UK, where most local commissioners have relatively little experience of cross-border healthcare, capacity-building and clear guidance on the legal framework and its application in the NHS will be needed to support implementation.

Although not directly affected by provisions on cross-border healthcare, discussions in this area also highlight questions about eligibility to NHS funded healthcare. Under current arrangements, it can be extremely difficult, in practice, to determine whether an individual is entitled to NHS-funded treatment, for example, in the case of individuals dividing their time between the UK and another EU country. A number of contributors have said that they would welcome clearer guidance on these issues.

Conditions for accessing healthcare: local eligibility criteria and procedures

We understand the current EU framework, and the proposals in the draft directive, to be based on the principle that patients should be eligible for reimbursements towards the costs of healthcare received in another EU country only to the extent that they would have received the same healthcare at home. So, for example, if a patient’s commissioner/insurer had decided not to fund a particular treatment for them, the patient could access that treatment in another EU country, but would have to pay for it themselves and would not be eligible for a reimbursement towards the cost. Contributors were clear and unanimous in the view that this principle is correct and it is crucial that it is preserved.

In relation to this, many contributors highlighted the fact that the NHS does not have national level eligibility criteria for determining access to particular treatments or a defined “basket of care” which NHS patients are automatically entitled to receive. The treatment which an individual can receive is determined at a local level, based on their particular health needs balanced against the health needs and priorities of the wider local population.

Access to specialist care in the NHS is by referral from primary care, and decisions about an individual’s care are usually taken by their NHS clinician, where relevant taking into account, or with reference to, local commissioners’ guidance on low priority treatments. Contributors were again unanimous in the view that the legal framework must recognise the legitimacy of local priority-setting and allow for the “gatekeeper function” and local decision-making processes to continue.
Contributors noted that if NHS patients have sought treatment abroad without a needs assessment from an NHS clinician, it may be extremely difficult to determine retrospectively whether treatment would have been available under the NHS, and therefore, whether the patient is eligible for a reimbursement.

For example, the NHS will not normally fund the removal of moles for cosmetic reasons but mole removal for biopsy where cancer is suspected is funded. However, after the procedure has taken place there may be no way of proving whether the procedure was for medical or cosmetic reasons.

**Supporting patients opting for cross-border healthcare: prior authorisation**

In England, patients referred for specialist care can choose to be seen by any provider contracted with the NHS to provide the appropriate treatment. This is referred to as “patient choice” and is a relatively new development (introduced in April 2008, after a gradual phase-in). It is in this context that many NHS organisations considered the proposals on patients’ rights in cross-border healthcare, and many felt that cross-border healthcare could be viewed as an extension of patient choice.

Contributors therefore considered that, where it has been established that a patient is eligible to receive a particular treatment, the fact that healthcare could be provided locally should not, alone, be a reason to prevent the patient from seeking treatment abroad. It was, however, felt that patients should be advised of local options where they existed, as well as being given information about their rights to access healthcare in other EU countries.

One key difference between patient choice in England and cross-border healthcare is that patient choice is limited to providers contracted to the NHS. This includes a range of independent and third sector providers, but crucially, all are required to provide healthcare according to NHS standards and conditions. By contrast, in a cross-border situation, a patient can access treatment from any healthcare provider, private or state/public sector, and without reference to issues such as compliance with quality and safety standards. This difference lay at the heart of a large proportion of contributions to the consultation.

Contributors were generally concerned about standards of quality and safety in providers overseen by systems they were not familiar with. Furthermore, a particular concern was raised around the issue of different clinical practices in other countries, which may have implications for patient outcomes and potential complications. In England and Wales evidence-based guidance on the appropriate treatment and care of people with specific conditions is produced by an independent body, the National Institute for Health and Clinical Excellence (NICE). Whilst NICE guidance is not binding, NHS providers would be expected to take it fully into account in deciding what treatment is appropriate for patients.

A specific example raised was In-Vitro Fertilisation (IVF) treatment for fertility problems. NICE guidance recommends that a maximum of two fertilised embryos are put back into the womb in a cycle of treatment. This is because multiple pregnancies are associated with increased risks of problems during pregnancy and labour, including an increased risk of premature birth. Respondents were aware of cases of UK patients travelling to other countries where similar guidelines did not apply. The motivation was that clinics could indicate a higher success rate in terms of clinical pregnancy. However, this was achieved by putting more embryos back into the womb, with a consequent increased risk of multiple pregnancies and increased risk of complications for both mothers and babies at a later stage.

This example illustrates why a number of contributors were concerned about whether patients would, in reality, be able to make informed decisions about suitable providers in other countries if they wished to seek cross-border healthcare. From the NHS perspective, a patient can be assured that an NHS provider will take into account relevant clinical guidance, but this is not the case for cross-border healthcare, and therefore additional information will be needed to support informed choice where cross-border healthcare is considered.

In view of this, contributors very strongly supported the use of prior authorisation systems as a mechanism for providing patients with clarity on matters such as what specific treatment their clinician recommends for them, what reimbursements they will be eligible for and what costs they will have to meet themselves, arrangements for any after-care needed and what will happen if anything goes wrong.

Provided that prior authorisation systems met criteria such as transparency and proportionality, were simple and straightforward for patients to use, and gave timely responses to requests, contributors did not feel they would constitute an undue barrier to accessing cross-border healthcare. On the contrary, many contributors viewed such systems as being essential to protecting patients’ interests by ensuring that they understand the conditions that apply to cross-border healthcare, in terms of quality and safety, potential differences between services and financial arrangements.

16 Different arrangements apply in Scotland, Wales and Northern Ireland.
Contributors felt that the provisions in the draft directive, which envisage that prior authorisation systems could only be compulsory in exceptional circumstances, were inadequate. In particular, the distinction between hospital and non-hospital is a false one, as the degree of risk and resource-intensiveness of healthcare can depend as much on the individual circumstances of the patient as the degree of complexity of the treatment itself. In addition, the need to plan services and manage financial resources applies equally to healthcare provided in hospitals and in other settings.

In view of this, it is likely that NHS commissioners would encourage systems of prior authorisation on a voluntary basis if the legal framework does not allow such systems to be mandatory on a routine basis.

Alongside this, some contributors suggested that EU healthcare providers who wished to provide services to NHS patients could sign up to NHS terms and conditions and be placed on the NHS “choice menu”. It was suggested that in such circumstances, as packages of treatment would be matched to UK practice and prices, different arrangements could apply such that prior authorisation might not be required. However, it was recognised that different systems of regulatory oversight might make such arrangements legally complex to realise in practice. Guidance on the feasibility of such approaches would be welcome as part of the implementation process.

**Limiting the right to travel for treatment**

In most cases, where it has been established that a patient is eligible to receive a particular treatment, contributors felt that if patients had made an informed choice to seek treatment abroad that they should be free to do so. However, contributors did suggest that in certain exceptional circumstances, it might be appropriate to restrict a patient’s right to travel to obtain healthcare. Examples given included: patients with a highly contagious and dangerous infectious disease, patients requiring care in a secure psychiatric facility, and prisoners.

Some contributors also presented the view that limiting the right to travel for treatment may be necessary in certain low volume, highly specialised services where a small reduction in caseload could threaten service viability. For example, clinicians may need a minimum caseload in order to maintain their levels of expertise in treating rare or highly complex conditions. The strong view was that any patient refused access to treatment abroad should be able to obtain a clear explanation of how and why the decision had been reached.

The draft directive appears to give little scope to providers to refuse to accept incoming patients, and contributors felt it was important to be clear that nothing in the draft directive interferes with the right of a provider to refuse to accept a patient for a specific treatment if the provider deems it clinically inappropriate to treat that patient, or the provider is unable, eg for reasons of limited capacity or expertise, to provide adequate or appropriate treatment to that patient.

**Costs, mechanisms and levels of reimbursement**

Contributors felt it was very important that all parties were clear about costs and levels of reimbursement in cross-border healthcare. Where it has been established that a patient is eligible to receive a particular treatment and they elect to receive that treatment abroad, most contributors agreed that reimbursement should be limited to the amount that the same treatment would have cost the home system.

Contributors noted that in practice, however, this is likely to present particular challenges, relating to both incoming and outgoing patients, in calculating the “NHS cost of care”. Although the NHS in England operates a system of tariffs for healthcare, not all treatments are subject to tariff, and for those that are, prices are factored to take account of local costs, so there is not, in reality, a standard price for any treatment. Furthermore, a tariff may cover a package of care, rather than a single procedure, and therefore costs may need to be “unbundled” if a patient receives a different package of care in another EU country.

Whilst the majority of contributors did not think these problems were insurmountable, several felt that national guidance on the calculation of costs and reimbursements would be needed to provide greater clarity to patients and local NHS organisations.

Under the provisions of the draft directive, the patient must meet costs up front, and must cover costs that would not be incurred if they were treated at home, such as travel costs. If treatment is more expensive abroad, the patient must cover the difference. If, however, treatment is cheaper abroad, the patient cannot be reimbursed more than they have paid—ie they cannot make a profit. Contributors supported this approach, as it was felt that a patient’s choice to be treated outside the UK should not lead to higher costs for the NHS, thereby reducing the resources available for the wider population.
Concerns were raised that patients might seek treatment abroad without being aware that the reimbursement they are eligible for may not cover their full costs of treatment. Contributors considered that this was another argument to support the use of prior authorisation systems.

Whilst some contributors suggested that treatment costs might be paid directly from the patient’s commissioner/insurer to providers in some cases, removing the need for patients to pay upfront, there was no support for this to be a universal requirement. Indeed, because patients are able to “top-up” their cross-border healthcare with additional treatments or services that would not be funded at home, and because some systems require patients to make a co-payment, it emerged that paying the provider directly could, in practice, be extremely complicated and less transparent for patients.

Furthermore contributors felt that payments from patients to providers would avoid potential difficulties with large scale and potentially bureaucratic systems for processing and securing payments between healthcare systems, and reduce difficulties associated with following up debtors from other countries where monies are outstanding at the conclusion of treatment.

Health inequalities and cross-border healthcare

The issue of equity is challenging and there was no clear consensus amongst contributors as to what impact the proposals would have on inequalities. A range of issues such as the state of an individual’s health, geographical factors, family and work commitments, how articulate and well-informed a patient is, the ability to speak another language, as well as their financial position, will all affect an individual’s ability to seek treatment abroad.

In general, contributors felt that rights’ to access cross-border healthcare should be well publicised, so that patients were aware of the options. However, where treatment could be provided in a timely manner in the UK and patients are deciding for personal reasons to seek treatment in another EU country, contributors felt that they should not confer a special advantage over patients who are unable or unwilling to do so. They should, therefore, as a general rule, be responsible for costs which would not be incurred if they received NHS-funded treatment in the UK.

The NHS has a “Healthcare Travel Costs Scheme” to support patients who have financial difficulties with travel costs associated with accessing healthcare. Contributors were not clear to what extent this scheme could apply to cross-border healthcare, but many felt it provided a framework that could usefully be extended.

Many contributors felt that, where there was a particular need, NHS commissioners should have flexibility to make special arrangements on an individual basis to cover costs of treatment abroad upfront and/or pay additional costs if care was more expensive. However, it was not clear whether contributors were always aware of existing options under social security arrangements (the “E112 referral”), or whether they felt a different mechanism was needed within the framework of the cross-border healthcare provisions. In view of this, guidance on the various options available to NHS commissioners would be helpful.

Requirements relating to information on cross-border healthcare

The point that emerged most consistently from contributors was the need for patients to be able to obtain good quality information about their options, including treatment abroad, in a way that enables them to make informed decisions about their healthcare. Consideration will need to be given to the provision of information in accessible formats and potential extra help or support for vulnerable patients or those with complex needs.

Many contributors were concerned that local NHS organisations and clinicians lack the knowledge to advise patients on their rights in cross-border healthcare or to direct them to where they can find out more about these. As a result, there were strong calls to be realistic about the level of information that local clinicians and services will be able to provide, and for national guidance and support in this area. Involving public and patients in the development of guidance and information on cross-border healthcare would be helpful in trying to dispel misconceptions and misunderstandings about what exactly patients are entitled to.

A number of contributors were interested in exploring options for shared resources or expertise. Whilst the idea of a national contact point was thought to be potentially useful as a source of information about other healthcare systems, it was noted that information would also be needed at a local level to reflect the level at which decisions are made in the NHS.

Contributors were also clear that provisions relating to the availability of information and data collection on cross-border healthcare should not place new costly, bureaucratic burdens on NHS organisations. It was suggested that a useful approach might be to collect data on a sample basis.
What happens when things go wrong: issues of liability and redress

Based on experiences of patients seeking treatments not available under the NHS, such as cosmetic procedures, in other countries, many contributors raised concerns that some patients may have unsuccessful or incompetently undertaken treatment abroad. Whilst the number of patients affected is, overall, likely to be small, contributors felt that this further supported the need for a system of prior authorisation, which could help equip patients with the information they need in order to be able to choose the best treatment for them and a safe and high quality healthcare provider.

In this context, contributors noted that is important that local NHS organisations and clinicians are able to help patients make a decision about where to receive healthcare without liability being conferred upon them if something goes wrong.

Contributors supported the position set out in the draft directive that it is the systems of the country where healthcare is provided that apply in terms of liability and redress when things go wrong. However, concerns were raised about the draft directive’s focus on compensation rather than wider redress (which can include a range of steps such as regulatory action, changes in practices, action to rectify a problem). Furthermore, the definition of “harm” proposed in the draft directive was identified as very problematic and contributors suggested that a reference to “adverse events” or a definition based on avoidable incidents arising from negligence which resulted in serious harm, should replace this.

There was no support from contributors for the development of international out-of-court settlement schemes as proposed in the draft directive. This was because contributors thought the situation was simply too legally complex.

Provisions relating to cooperation in the field of healthcare

The Commission’s proposals also include a number of provisions designed to promote cooperation between EU member states, in areas such as the establishment of European reference networks (ERNs) of healthcare providers, e-health and the management of new health technologies. Some contributors expressed an interest in the development of ERNs particularly with regards the development of specialist services in other EU countries, however no specific views were expressed on whether the inclusion of this provision in legislation would be helpful or not.

Contributors did raise concerns about proposed provisions on mutual recognition of prescriptions, e-health and health technology assessment. These all related to concerns that the proposed provisions were too far-reaching and risked cutting across existing national or local decisions or ongoing work in these areas.

In particular, contributors were concerned that the draft provision on recognition of prescriptions was unclear and open to misinterpretation. For example, some contributors thought this provision could be read as conferring rights to reimbursement for medicines not funded by a patient’s health system, or placing an obligation on clinicians to administer a drug not licensed in the member state they work in. Contributors were strongly opposed to either of these propositions and felt it was important to clarify that this was not the effect of the proposed provision.

January 2009

Supplementary memorandum by the Royal College of Nursing

During the oral evidence session from the RCN to EU Sub-Committee G Inquiry on cross border care we were asked to provide supplementary evidence.

At the end of the oral evidence session Lady Howarth raised the issue of proportionality and understanding the different systems in place across the EU.

The RCN believes that the government in this country needs to ensure that patients can be advised on how to access cross border care whilst meeting the requirements of the directive. Given that any decision to seek treatment in another country cannot be isolated from considerations about options for treatment in the home member state (most patients preference), wherever possible it is sensible to integrate information and advice on treatment outside the UK, with processes in place to advise on options locally/nationally.

Consideration should also be given to ensuring that information provided to facilitate choice and cross border mobility is to a consistently high standard and that Member States demonstrate that they are taking steps to address the needs of population groups who traditionally have difficulty in accessing information.
The overriding concern of any government should be to prevent rising inequality of outcomes in respect of health and social care. The Directive should provide guidance to member states and emphasis the importance of cohesive health and social care services which improve the health and opportunities for citizens of the EU. In particular, the Commission may wish to consider what happens where member states costs are significantly lower than neighbouring states costs who may find it impossible to fund “greater” choice or mobility as reimbursement is only the level it would cost to provide the care in question within the host member state.

In terms of proportionality the Commission should be aware that this Directive will pose more of a challenge for some member states than others. The health care systems in some of the wealthier member states are already set up along lines which facilitate choice and provide a decent level of information for commissioners, providers and users of services. For example in England, the government has already invested significant resources in Choose and Book which attempts to provide greater choice and flexibility for planned care. Even with this investment, take up rates are still very low.

In poorer or less well resourced member states, there may need to be significant investment in staff training, public education and infrastructure to address the aims of the Directive. The impact of this Directive in terms of the sustainability of services and patient flows across borders should be closely monitored.

If you require further information please do not hesitate to contact me. Once again thank you for allowing the RCN to contribute to this important investigation.

15 December 2008
CROSSBORDER HEALTHCARE : EVIDENCE

THURSDAY 11 DECEMBER 2008

Present Cotter, L Kirkwood of Kirkhope, L
Howarth of Breckland, B (Chairman) Lea of Crondall, L
Inglewood, L Morgan of Huyton, B

Memorandum by the British Dental Association (BDA)

SUMMARY

1. The British Dental Association is the representative organisation for the dental profession in the UK, with 20,000 practising dentist members in all spheres of dental practice, comprising about two-thirds of the profession.

2. We welcome publication of the Commission’s proposal and support many of the measures, which are designed to clarify patients’ rights, protect patient safety and improve the quality of service and sharing of information and good practice. We believe that there will be important implications for the UK, whose health service has not been based on explicit patient rights, clear authorisation of rights of access and set reimbursement. We note that the NHS Constitution will address some relevant issues, but in its current form it does not go far enough. A framework directive will necessarily leave many issues unresolved and we can see that there will be not only a great deal of debate, controversy and work to do in applying the provisions to the UK, but there will be many challenges to decisions taken at all stages.

RESPONSES TO SPECIFIC QUESTIONS

What do you see as the general advantages and disadvantages of patients having the right to obtain healthcare in Member States other than that where they reside? In what circumstances might patients seek to exercise any such right?

3. In dentistry, although there has been much publicity given to dental patients travelling abroad, a relatively small number seek care overseas. Those who do, do so for two reasons: first, they have been unable to obtain NHS care in the UK and believe that they can obtain care more quickly and more cheaply elsewhere; and, second, that they seek complex and expensive restorative or cosmetic treatment that is obtainable in some member states at lower prices than in the UK.

4. To patients who seek this swift and cheaper care, the advantages appear obvious but they can be deceptive. The main problem arises in the case of complex treatments such as implants that require aftercare and are more likely to go wrong. UK dentists have found that some patients returning from overseas care look to them to put right treatment that might have failed and are unable to get redress from the overseas practitioner. We are pleased to see that the proposed directive addresses this issue and makes very clear where the responsibility lies. That does not mean that in practice it will be straightforward when patients return home soon after treatment.

5. A recent BDA survey (March 2008) found that just under half of respondents had a patient who had gone abroad for treatment and just over half of those had treated a patient for complications resulting from treatment received abroad. Infections, pain and poor quality of initial treatment were the most common complications.

What problems do you think have arisen as a result of the present uncertainty in respect of EU citizens’ rights to obtain such cross-border healthcare and to have the costs of this reimbursed by the Member State where they reside?

6. We are concerned at the inconsistency in decision-making and of care availability throughout the country and this problem is the more acute for patients who wish to seek care abroad and do not know whether and to what extent they will receive support. Much needs to be done at national level to determine patient rights before the UK will be in a position to implement the directive and it is inevitable that it will be controversial.
What need do you see for EU level action in this field and, if you do see such a need, what objectives should such action have?

7. Case law, while it might clarify the Community legal position and apply the principles of the Treaty, is an unsatisfactory way of protecting rights in a situation where an increasing, if relatively small, number of Community citizens wish to take advantage of freedom of movement and to exercise choice. We believe that most patients will continue to prefer to obtain care close to home, but it is important that their rights and responsibilities are clear if they choose not to do so and that they are appropriately protected.

What is your view of the extent to which the Commission’s proposed directive will meet the objectives, if any, that you judge action at Community level should have?

8. The directive is a significant step forward but, as a framework directive, it leaves many areas still unclear and we can see that there remains much to be resolved in the courts, whether nationally or at ECJ level, and/or through subsequent legislation or regulation. These areas include how member states develop a reimbursement tariff and the decisions they take on the availability of care, what regional variations there may be, what bureaucratic and prior authorisation obstacles they seek to impose on patients and whether member states are required to provide care for nationals of other states.

What conditions, if any, do you feel that Member States should be allowed to impose on citizens’ rights to seek healthcare in another EU country—and to what extent do you think the draft directive satisfactorily makes provision for these conditions?

9. The Commission appears to wish to keep matters simple and impose as few conditions as possible. We support this approach as it will help to minimise the need for yet further case law. As for the provision that member states may impose the same conditions as in the home state, the UK still needs to define those conditions and ensure that UK nationals can refer to transparent and consistent prior authorisation criteria and funding arrangements. Special attention should be given to NHS organisations in areas where there may be a disproportionate number of patients wishing to travel as their ability to sustain essential services locally may be adversely affected.

What limits, if any, do you think there should be to the level of costs which Member States should be obliged to reimburse to citizens who obtain cross-border healthcare—and to what extent do you think the draft directive satisfactorily makes provision for these conditions?

10. Prior authorisation requirements will be acceptable if they avoid a serious threat to the financial balance of the member state’s social security system, capacity to provide treatment, planning and so on. While these provisions are clearly essential, it is by no means clear how they will be interpreted. It is essential that the financial viability of member states’ health services are not threatened by the provisions and the costs of implementing the arrangements must be proportionate. We also do not yet understand how a requirement for a GP referral, where necessary in one member state, could work in practice and look forward to that becoming clearer.

What is your view of the likely practical impact of the proposals and of how they would affect day-to-day healthcare provision in the UK? For example, could language difficulties present an obstacle? Who should be responsible for aftercare (out-patient and in-patient)?

11. We support the proposal that funding should be to the level that would have been borne in the home state.

What limits, if any, do you think there should be to the level of costs which Member States should be obliged to reimburse to citizens who obtain cross-border healthcare—and to what extent do you think the draft directive satisfactorily makes provision for these conditions?

12. We cannot estimate the extent to which patients might take up these new rights and how it might affect the NHS, but we can see that there will be very significant work to do in interpreting and applying them in the UK and in developing a uniform regime throughout the country.

13. We know from the influx of dentists from within and outside the EU over the past few years that language and cultural differences can be very significant barriers to effective health care and particularly patient understanding and expectations of care. It will be for the host member state to regulate services provided for visitors and to ensure that they have all the information they need and know how to get redress if necessary. Healthcare professionals and providers will have to be aware of their responsibilities for obtaining valid consent in these circumstances. In practice, however, home member states are bound to be called upon to provide aftercare since patients are likely to want to return home as quickly as possible after treatment.
What is your view of the need to limit the medical conditions for which treatment could be sought in this manner?

14. As above, we agree with the approach in the directive. Once again, there will be a need for the NHS throughout the UK to be clear on the matter so that disputes and legal claims are avoided as far as possible.

How important do you feel it is to ensure that opportunities to benefit from rights to cross-border healthcare are, in practice, made equally available to all citizens and are not confined to just the wealthy or well-educated who may have the knowledge and ability to take advantage of their rights?

15. It is essential that there is no discrimination and we reiterate the need for uniformity of access, information and rights. Where the UK’s health service might have difficulty in providing necessary care within a reasonable time, it is up to it to have mechanisms available to assist patients to obtain care elsewhere. There are good examples already of commissioning from mainland Europe. But we do not believe that patients for whom care is available in the UK should necessarily be helped by the state to seek care elsewhere just because they would like it. Ease of reimbursement will also be an important factor in equality of access.

How do you think the aim of such equality of access should be achieved and to what extent do you feel that the draft directive is satisfactory in this respect? To what extent, for example, are the provisions on the availability of information sufficiently robust?

16. We support the establishment of central contact points and the need for cooperation and sharing of information between states. But we also know from 30 years of freedom of movement of professionals that this will be very difficult to achieve. We do not see how this directive can be more explicit, however.

What are your views on the provisions set out in the draft directive for cooperation between Member States, including: the mutual recognition of prescriptions; the establishment of European reference networks of healthcare providers; e-health; and the management of new health technologies?

17. We support these measures to enhance quality and safety, improve patient care and increase cost-effectiveness. They are very long-term projects, however.

25 September 2008

Memorandum by the British Medical Association (BMA)

The British Medical Association (BMA) is an independent trade union and voluntary professional association which represents doctors from all branches of medicine all over the UK. It has a total membership of over 139,000. The BMA has closely followed developments around cross-border mobility for the past five years. It has submitted a response to the European Commission’s recent proposal and is pleased to contribute evidence to the House of Lords Sub-Committee G inquiry.

Executive Summary

— The BMA welcomes the publication of the European Commission proposal and agrees with the principle of cross-border patient mobility.
— The BMA calls on the European Commission to ensure that the proposal does not impose an unnecessary administrative burden and that it emphasises the importance of quality and safety in all healthcare.
— It is important that non-discriminatory national rules for the provision of healthcare, such as the gatekeeper role of GPs, are respected.
— The BMA calls on member states to ensure that patients are not prevented from exercising their rights to cross border treatment due to financial constraints and that equality of access is guaranteed.
— The BMA has concerns over the lack of clarification on continuity of care and the linked issue of language and translation provision.
— The impact of the proposal on current NHS provisions such as the ability of patients to obtain care across national UK borders, the issue of “top-up” payments and the NHS Healthcare Travel Cost Scheme must be examined.
— The proposal presents opportunities to improve access to information on the quality of healthcare across the EU and on the types of treatment offered.
The sharing of patient data, the use of e-Health and systems of compensation and redress need to be examined further.

**Necessity of Legal Clarification of Patients’ Rights**

1. The BMA welcomes the publication of the European Commission proposal for a directive on the application of patients’ rights in cross-border healthcare. Following the adoption of the Services Directive\(^1\) and the recent rulings of the European Court of Justice on cross-border patient mobility\(^2\), the BMA believed that legal clarification of the position of EU patients was vital. The present legal uncertainty surrounding the issue of patient mobility has resulted in unequal access to care abroad with only those patients willing and able to undertake legal action exercising their rights under EU law.

2. In principle, patients should and want to be treated as close to home as possible. National healthcare systems should be designed and organised in a way which ensures that all patients have access to high-quality care close to home and without undue delay. However, the BMA agrees that when this is not possible, patients should have the option to travel to another EU member state for treatment which is paid for by their home healthcare system. In this respect, the BMA welcomes the principle of greater choice for patients.

**Objectives of EU Action**

3. The BMA calls for any new directive to respect the principle of subsidiarity and to recognise the fact that EU healthcare systems differ considerably across the 27 member states. The new rules should clarify existing patient rights under EU law but should not impose any unnecessary administrative burdens or financial costs which would ultimately be detrimental to the provision of safe, high-quality healthcare for all. At all times, patient safety and the provision of high-quality clinical care should be the overriding priorities of any new legislation.

4. To this end, the BMA welcomes the emphasis on quality and safety which is inherent throughout the proposal. In a modern healthcare system with an increased emphasis on patient safety, it is essential to demonstrate that both member states and healthcare authorities have fulfilled the appropriate safeguard criteria. The BMA welcomes the establishment of guidelines which would facilitate the implementation of a common set of quality and safety principles and would welcome the participation of healthcare professionals in the writing of these guidelines. Indeed, the BMA would encourage the introduction of a set of minimum quality standards for healthcare in Europe, overseen by the European Commission, in order to ensure the highest possible level of healthcare across the continent.

**National Conditions for the Receipt of Care**

5. The BMA believes that it is essential to respect non-discriminatory national rules and processes which are used to effectively plan healthcare in the various member states. We therefore support the fact that the proposals safeguard the gatekeeper function of GPs in the UK and respect a member state’s right to define its own national basket of care. Thus the BMA supports the provision in the proposal which allows member states to remain free to establish a list of available treatments that will or will not be provided under their own health care arrangements.

**Levels of Reimbursement**

6. The BMA has concerns regarding the possibility that healthcare may be more expensive abroad and that the patient would be expected to pay the difference in cost. Whilst we agree with the principle that the level of reimbursement should be no more than the cost of treatment in the home healthcare system, we believe that this co-payment may have a negative impact on equality of access. Thus the BMA calls on member states to ensure that patients are not prevented from exercising their rights to cross border treatment due to financial constraints. Member states will have to establish extremely clear rules for systems of reimbursement if this new directive is not to provoke a new spate of European Court of Justice cases.

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1. Directive 2006/123/EC
2. C-158/96 Kohll; C-120/95 Decker; C-368/98 Vanbraeckel; C-157/99 Smits & Peerbooms; C-372/04 Watts
PRactical Impact of Proposals in the UK

7. A concern for the BMA is the lack of clarification regarding continuity of care. Effective communication between clinicians and healthcare systems in both the sending and receiving countries must be ensured. Continuity of care should be ensured by a unified system of handover between clinicians as language problems and different decision making procedures may impact on patient safety. The BMA has particular concerns over the cross-border treatment of certain illnesses such as mental health and chronic physical disability where the importance of the clinical relationship and knowledge built up over the course of several consultations cannot be overestimated. Patients must be aware of such concerns and these must be taken into consideration when opting for cross-border treatment.

8. Further clarity is needed on the provision of language support to patients receiving treatment in a foreign country. It seems an unfair burden to expect the receiving country to provide services such as interpretation and the translation of medical notes. However, patient safety considerations mean that the language issue should be urgently addressed and the BMA calls for further work to be undertaken on this issue.

9. In the UK, the ability of NHS-funded patients to secure treatment abroad has implications for equity. Effectively, patients placed lower down a waiting list for reasons of clinical priority but who are willing to be treated abroad might not only get treatment more quickly than those higher up the list who prefer to be treated in the UK, but—depending on reimbursement arrangements—might even delay the treatment of UK patients. The BMA calls on the UK authorities to ensure that no patient is put at a disadvantage from the new proposals by having their treatment delayed in such a way. This new directive must not compromise standards of care for people who choose to stay in their home country, or who are unable to travel abroad for treatment.

10. A further aspect of equity is that, under current NHS arrangements, patients in one part of the UK are not free to seek treatment, as a matter of right, in another part where waiting times are shorter. Yet they would be able to seek such treatment in another EU country. This can be viewed not only as an anomaly, but also as inequitable to those who might consider treatment elsewhere in the UK but who are denied that option by UK rules, and who for whatever reason will not contemplate seeking treatment abroad. The BMA believes that the introduction of an inter-state mechanism allowing for cross-border healthcare may also provide a template for the resolution of the issue at intra-state level.

11. The proposed introduction of the cross-border recognition of prescriptions may also pose a problem in the UK. Whilst the proposal respects a member state’s right to only reimburse the drug if it is in the home basket of care, it makes no mention of patients’ entitlements to continue to receive publicly funded treatment if they chose to pay for the drug out of their own funds. Current UK guidelines suggest that those UK patients who “top-up” their NHS treatment by paying for drugs that are not publicly funded, lose their right to continue to receive NHS treatment for that episode of care. This area is currently under review and further clarification is expected in autumn 2008.

12. Clarity is needed on whether the UK can impose such a condition on UK patients who receive a prescription for an authorised, but non-publicly funded drug from a second member state and who wish to pay for the drug themselves. To deny the patient may be viewed as a restriction of their rights as provided under the proposal.

13. The BMA further questions the impact of the proposals on the NHS Healthcare Travel Cost Scheme which provides financial support for certain low income patients to travel to hospital. As qualifying patients would be eligible for this if they were treated in the UK, it would be discriminatory to refuse the reimbursement if they travelled outside of the UK for treatment. This may have a potentially destabilising affect on the finances of the NHS and needs to be examined in further detail.

Equality of Access

14. The BMA remains concerned that the proposal must not be allowed to erode the fundamental values of universality, accessibility and equality that underlie healthcare. Healthcare provision should be equal for all EU citizens regardless of whether they have the ability to travel abroad for treatment. Patient mobility must not just be for the wealthy and educated: equality of access must be guaranteed.

15. The BMA believes that equal access to care abroad may be compromised by the need for a patient to pay up-front for care received abroad before seeking reimbursement. It is essential that member states introduce

an equitable system which provides full reimbursement with a minimum of delay. An extension of the EU Late Payments Directive\(^4\), which is currently under review, may be one method of ensuring swift reimbursement but other financial mechanisms must also be explored.

16. In the interest of providing clear and transparent information, the BMA suggests that national healthcare systems provide easily accessible and understandable information on the contents of its national basket of care and on the cost of each treatment. Whilst this already exists in many member states, the BMA believes that the compilation of a list of treatments and corresponding costs may provide domestic benefits in the UK by informing patients of the actual cost of their publicly funded treatment.

17. The BMA welcomes the proposal to establish national contact points which will provide information about the process for accessing cross-border healthcare. The BMA is pleased that this added administrative burden will not fall on medical professionals, particularly family doctors, who should not be expected to organise cross border treatment. In addition to providing information on process, redress and financial considerations, we also wish the national contact points to provide information on more practical considerations such as the differing cultures of care that exist across the EU member states. When choosing to undergo treatment in a member state other than his/her own, patients must be fully aware of different cultures and traditions of care which may impact upon their decision to access such care abroad.

18. The BMA believes that there may be a role for the European Commission or another independent European organisation to provide information on cross-border care. If every member state is expected to provide in-depth information on the healthcare systems of 26 other countries, the administrative burden will be heavy, particularly for smaller member states. A single Internet portal could provide this information leaving national contact points to provide more detailed answers in response to an individual patient’s queries. Such a portal could also be used to encourage member states to provide a comparable data set on the availability of treatment and on the quality of care and treatment outcomes. The portal must allow for regional variations within a member state and will provide a useful tool in highlighting regional disparities.

**Cooperation between Member States**

19. The BMA believes that there needs to be a mechanism for sharing patient data between clinicians in both the patients’ home country and the country where they receive treatment. Clinicians in both countries must be able to communicate effectively and to exchange medical records in the language of the patient’s country of origin. Whilst high level recommendations are in place for cross border interoperable systems the practicalities of delivering interoperable systems needs much more detailed consideration. Many issues, which have presented a challenge for individual countries, could be magnified when applied to this scale. Questions remain such as how will the language barriers, differences in structuring and recording information be managed? Whilst SNOMED\(^5\) may assist, there will still be parts of the record in free text. There are also information governance and data quality issues which need further exploration. It is very unlikely that e-Health systems will be fully interoperable by the time that this proposal is implemented across the EU.

20. The BMA welcomes the clarification that healthcare providers must fulfil the regulatory requirements in the practicing country rather than in their country of origin. However we argue that this makes it even more essential that member states are able to share their respective regulatory data and should be able to verify the eligibility of professionals to practice. This could be in the form of a certificate confirming an individual’s good standing and fitness to practice. We would also call for the concept of regulatory redress to be added to the proposal. Whilst the proposal clarifies the system for financial redress in the event of healthcare-related harm, the BMA believes that the concept of regulatory redress should also be added.

21. Further, the BMA calls on member states to implement a comprehensive system of redress and compensation for patients who suffer unexpected or avoidable harm as a result cross-border healthcare. As well as providing redress for patients, this system should allow for a mechanism by which the home member state has recourse for claiming compensation for the cost of rectifying clinical mistakes made by the country of treatment.

*September 2008*

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\(^4\) Directive 2000/35/EC

\(^5\) SNOMED CT (the Systematised Nomenclature of Medicine Clinical Terms) is a clinical terminology. Using this computerised language allows clinicians to communicate in a standardised and consistent way
Examination of Witnesses

Witnesses: Dr Hamish Meldrum, Chairman, and Professor Vivienne Nathanson, Director of Professional Activities, British Medical Association; and Ms Susie Sanderson, Chair of the Executive Board, and, Ms Linda Wallace, Director of Professional and Advisory Services, British Dental Association, examined.

Q282 Chairman: Several of our members are down with either colds, flu or ear infections, which, as you know, is running through. I do apologise that we do not have the numbers in the Committee that we normally have. Having said that, can I welcome you and say how grateful we are that you have taken the time and trouble to come and talk to us about what we think is an important inquiry. Although this issue is not likely to affect a huge number of people, one of the questions one of our members who is not here keeps asking is “Is it worth doing?” We know it is worth doing—and we hope you are going to tell us—because unless we have it, we are not going to have a framework in which these issues can be dealt with, so it is important that the Directive is clear on a number of issues, and I know your evidence says that. At the end of the session if you want to submit supplementary evidence, you may do so. I am going to ask the witnesses from the British Dental Association followed by the witnesses from the British Medical Association to state their names for the record and their titles. Although we can see them, we have to have you say who you are. And then, if you wish, you may make a short opening statement, and then the members will go ahead with the questions, which you knew in advance. However, there may well be supplementaries or alternative questions which members wish to ask.

Ms Wallace: Linda Wallace, Director of Professional and Advisory Services at the British Dental Association.

Ms Sanderson: I am Susie Sanderson and I am Chair of the Executive Board of the British Dental Association.

Dr Meldrum: Hamish Meldrum. I am still a practising GP one day a week (so consultations afterwards!) but the rest of the time I am Chairman of Council at the British Medical Association.

Professor Nathanson: Vivienne Nathanson, Director of Professional Activities at the British Medical Association.

Q283 Chairman: Dr Meldrum, we are particularly pleased to see you because the Royal College of General Practitioners did not manage to get here and we had questions that we particularly wanted to ask them, so you may find yourself with more supplementaries than you expected.

Dr Meldrum: I am also a Fellow of the Royal College of General Practitioners and they have spoken to me about the fact that it was illness that prevented them from coming.

Q284 Chairman: Can we just move in then and can I begin by talking about the present uncertainty that arises from the legal processes around cross-border healthcare, really highlighted by European Court of Justice cases such as the Watts case. The BDA has identified a number of issues around that uncertainty in its evidence, and expresses the view that much work needs to be done in the UK to determine patient rights before the Directive can be implemented. Could you expand on that comment. Do you consider that the draft Directive as it stands cannot be applied to the UK, for dentistry at least?

Ms Sanderson: We think that it probably can be applied for dentistry in the UK but dentistry is predominantly a primary care situation. Most dentistry is provided in the high street by general dental practitioners, and particularly in England and Wales the care for patients in dentistry has been devolved to local level. That was designed to provide care which is pertinent to local needs and funded at local level as well. It is a very long story but it does mean that every person providing care, and every person receiving care, is treated at a different value, so there is an issue over preparing tariffs, for instance, and there will be all sorts of legal challenges about fairness of reimbursement. That is one of our major anxieties about this. It is a framework Directive and we welcome the clarity that it will introduce once all those queries are ironed out, but I think it will be a very long process to do that. We also have a concern over the destabilising of budgets for the delivery of healthcare. I would not describe it as fragile, but we are always after more money in dentistry, and I think if the whole country’s dental needs were to be provided, we are already short of money, and I think removing that elsewhere would cause us some challenges.

Q285 Chairman: Do the BMA want to add anything to that?

Dr Meldrum: Not really. The only thing we find a little paradoxical, as my colleague has said, is that dentistry is very much almost a primary care-type of situation whereas most of the rest of this in healthcare is talking about secondary care issues and primary care is not involved. It seems a little paradoxical that that situation should apply.

Chairman: I am going to move on to Lord Inglewood who is going to talk about some of the guiding principles.

Q286 Lord Inglewood: Most of the evidence that the Committee has received suggests that the demand for cross-border healthcare is relatively small and, on the
whole, patients prefer to be treated at home. Given this is the case, and if you think it will continue, where do you think the balance should lie between a patient being able to receive appropriate primary treatment quite close to home and their right to travel elsewhere to receive treatment in cases where the waiting time is really unacceptable?

**Dr Meldrum:** There is already a situation where, as you say, if the waiting time is unacceptable, under the E112 regulations, that patient can apply to be treated abroad. Yes, I think in terms of the demand, it is quite difficult to judge. You are right, the majority of patients want good-quality care close to home where possible. There are one or two who may have individual reasons for wanting to travel. It may be slightly different on the Continent where travelling is often a lot easier between countries. I think you are right to highlight the problem between the balance of individual patients’ rights and having patient-centred treatments, but also the fundamental principles of the NHS of equity, of mutuality, and not allowing anything that might destabilise that. We saw in the recent debate on top-up payments these two sets of principles: individual patient choice and patients who have the ability to pay being allowed to do so but yet the fact that you did not want to create inequities within the healthcare system. The BMA’s view is that, whatever we do, we must not go too much beyond that you move on to say that the majority of patients want good-quality care close to home. I think you are primarily operating or all patients?

**Professor Nathanson:** We would say that the most important thing is to say, whatever else happens, we must protect patients and make sure that the quality of care and patient safety is paramount, and then beyond that you move on to say that the majority of patients are going to get their care from our own Health Service, so it is important not to destabilise that or to distort priorities within that and to say what are the benefits that could accrue from cross-border travel. We are not against cross-border travel; we just want to make sure that cross-border healthcare works in the interests of patients.

**Q288 Lord Inglewood:** Do you think in looking at that problem you should start from the proposition that we must not destabilise existing arrangements, or should it be done from the proposition that this is the way the Single Market works and we have got to accommodate accordingly the provision that you provide?

**Professor Nathanson:** We would say that the most important thing is to say, whatever else happens, we must protect patients and make sure that the quality of care and patient safety is paramount, and then beyond that you move on to say that the majority of patients are going to get their care from our own Health Service, so it is important not to destabilise that or to distort priorities within that and to say what are the benefits that could accrue from cross-border travel. We are not against cross-border travel; we just want to make sure that cross-border healthcare works in the interests of patients.

**Q289 Lord Inglewood:** You are defining patients as being patients within the jurisdiction within which you are primarily operating or all patients?

**Professor Nathanson:** All patients, Europe as well. If you destabilise a system it does not help those patients coming in for care either, and of course it does then start to lead you to uncertainty as to whether the patient, whether domestic or from overseas, will get the care that they need.

**Dr Meldrum:** I was just going to add that the further patients go away from their home for care, the more chance there is of problems with continuity, whether that is within the UK, or even more so outside, and then when you go outside you have the problems of perhaps language and different drugs and such like being used. I think in terms of patient safety one always has to be aware of these practical issues the further people go away from their own home base for care.

**Chairman:** And indeed these are questions that we will be coming on to with other members. This feeds directly into the prior authorisation question which I know Lord Lea wants to follow through.

**Lord Lea of Crondall:** It is called prior authorisation but in fact it gets into the nitty-gritty of the whole scheme. There is, presumably, some difference between a GP referral where you have things like waiting lists in the back of your mind, how would that work, and that is totally different from the BDA’s belief of a lack of clarity about how it would be interpreted in their field, so could you both have a go at it?
Q290 Chairman: Indeed, if the BDA want to say anything about the previous question; I tried to catch your eye but you did not respond.

Ms Sanderson: It will come in later, I am sure. I think we are concerned about the authorisation of referrals through a gatekeeper or the implication that there is a gatekeeper here. In dentistry of course we do refer patients but it tends to be to a consultant for an opinion and then for treatment, so we very rarely refer specifically for an item of treatment. The prior authorisation of that leads to all sorts of questions about the credibility of the referral. Is there a problem for the receiving clinician with the referring treatment plan for example? I have seen two sides to this as I have talked to other people. Is it to facilitate the reimbursement for the patient? Is it to make that an easier stage? In fact, is it to save that middle step, is it to allow the patient to be eliminated from that process so that the two states reimburse each other, or is it actually a facility for the home state to say, “No, you cannot go to another country to have this treatment done; you are better served here.” There are all sorts of debates around the prior authorisation and actually what it is for. In dentistry it is very unlikely because, as I said earlier, we are a primary care largely and patients will go away into another country for a specific item of treatment; quite often for things that they perceive to be either quicker or cheaper.

Dr Meldrum: I would echo much of that. It seems that there are two aspects to prior authorisation, one is the financial and the other is what I would call the clinical. Unlike many of our European counterparts, the system of primary care is much more developed in the UK, and whether you call it the gatekeeper, or as I would probably prefer the “navigator” role of general practice, it is the norm that people, before accessing secondary care, will have been referred by primary care. That does not always apply in certain of the continental European countries. My colleague has touched on the financial aspects of prior authorisation and whether that is in the patients’ interests to know that if they do go, they will get that money refunded, or whether it is in the countries’ interests to try and prevent or in some way limit the numbers who travel. The other aspect when we are looking at this is the rather vague definition of what hospital care is. It seems to be overnight hospital care whereas we know that there is an increasing trend towards day case surgery. I know there are some moves by certain European parliamentarians to get the definition changed, so there is confusion about the definition as well as aspects of prior authorisation.

Q291 Lord Lea of Crondall: Just on that last point, I mentioned waiting lists, and even if a bed is not involved (although often it is involved), and jumping

the queue and going somewhere else and so on, how do you see an inward referral from Holland or somewhere fitting in with the fact that we have got waiting lists?

Dr Meldrum: Well, I would expect the same rules to apply. I do not think there should be any queue-jumping. I do not think this facility should allow queue-jumping within countries. If the wait in the UK for a UK citizen is four weeks, then somebody coming from Holland should wait that four weeks as well.

Q292 Lord Lea of Crondall: If they were covered by their insurance scheme, it would not be NHS waiting times.

Dr Meldrum: But they are still using an NHS facility and if significant numbers were going to use that, it would be prejudicial to NHS patients. We are not talking about private care; we are talking about state-funded care, whether it be NHS or in the European community.

Ms Sanderson: And that is one of the provisions in the draft that we welcome, that it actually does say that the host country will use its own legislation or its own guidance when it is deciding how patients will be treated.

Q293 Chairman: I think you did say that there was no definition of prior authorisation.

Dr Meldrum: I said there were two aspects.

Q294 Chairman: Do you have a view about how that should be defined?

Dr Meldrum: I am a little bit on the fence on that because it really depends how it is going to be used. If it is going to be helpful to the patient, in other words save lots of delays in both getting money refunded and actually ensuring that money is refunded when they have sought treatment abroad— we are talking about UK patients—then one could see a system, whether you call it prior authorisation or prior approval, that what you are doing is legitimate, and I think it could be quite beneficial to patients. If it was going to be used by home countries as a way of unnecessarily limiting cross-border treatments, then one would not want to see that, so it is not so much whether or not there is prior authorisation; it is is how it is used that I think would be the fundamentally important point.

Q295 Chairman: That takes us into the next area really, which is about information and how people know what the system might be because, whichever of those it happens to be, the potential patient needs to understand the system, and we need to hear from you how you view that because we have found it difficult to get our witnesses to say how they think
this should function. In your written evidence you both welcomed the establishment of national contact points. What sort of information do you think these contact points should provide and how do you think it should work in practice? Where should it be established, who should be providing it, and how should it be funded? Do you consider that any other organisation should be involved in the provision of information on cross-border healthcare in the 27 Member States? How do you actually see it operating in practice?

**Ms Wallace:** I think we, too, are struggling to see quite how it might operate. Patients obviously are going to need to understand everything surrounding any question of moving for treatment, particularly the choices that they have, the quality, the standards, and also a lot about the culture, not to mention the costs. We think that that will be difficult to gather in many cases, just on the basis of our own experience of trying to gather information about dentistry in the other Member States. There have been two experiences: firstly, the experiences of the regulators, who quite often have difficulty in verifying the credentials of dentists coming to the UK; and also in our own research into the way dentistry operates, where we have a research project that is updated every three years on this, and it is an enormous task. We think it has to be centrally run and centrally funded but making sure that the professionals and patient organisations that are concerned have an input, because of course the patient organisations are going to know the sort of things that patients need. I think it is quite complex and quite costly.

**Q296 Chairman:** What does “centrally” mean?

**Ms Wallace:** Presumably, they would have to be nationally central but also the Commission, surely, must have a responsibility to facilitate the gathering of the information. I think it would have to be centrally funded. Again, whether that is centrally funded through the Commission or by national governments, I suppose it is all money coming from the same place in the end.

**Dr Meldrum:** Patients want clear, consistent information. Having had the so-called Choice Agenda in the UK for some time, I know as a GP that it is quite difficult actually getting clear, consistent, reliable information about UK treatments and hospitals. It has got to be many, many more times more complicated if you are going abroad as well. I would agree that the only way to get consistency is to have some central body, whether it is the EU Commission or whatever, actually monitoring and making sure that the information that is being provided is in a consistent form and that similar standards are being used to measure the things that are important. I do not think it is either possible or practical for individual GPs to have these discussions with patients. As I say, it is difficult enough even doing that within one’s own country, and I think to do it with lots of other countries would be extremely difficult, so that is why we would support some sort of central place that patients could go to get that information. However, like Linda, I do not underestimate the difficulty of doing that. The other question is actually what data are going to be important. Is it just about the car parking and the travel arrangements, or is it about the results that these hospitals have, the complication rates, infection rates, a whole lot of other things, which we are still only starting to get our heads round in this country, far less what it is going to be like in 27 different countries of the EU.

**Professor Nathanson:** In addition to that, you of course have to talk about the different cultures and traditions of care because the way in which care is offered may be significantly different in different countries, down to things like routes of administration of common drugs, whether you are expected to have family members there to offer some of the care, for example, helping to feed you if you are in hospital for a while. There are very different traditions in different places. Those things are of absolute key importance but they are not something that you would have to put in a document for British nationals knowing about British healthcare but you do need to when you are looking at other countries.

**Ms Sanderson:** And there is an issue of equity of access to that information as well. I would find it easy to go on the internet and have a look and work my way round that; I am not sure my mum would. That is just the inequity within one family, so across the population I think that is a real problem.
there is certainly a possibility that it will come from healthcare budgets. I am not sure that just restricting it to the more serious conditions is really the right way to go. There are two problems that I can see. It is actually sometimes the less serious things that are important to people that they want to have dealt with, and perhaps might want to have dealt with more quickly, and therefore may want to go abroad. If you are talking about people with very serious conditions, then that adds to the various complicating factors I was talking about in terms of continuity, all the travel arrangements, the time that they might have to spend in the other countries before they could travel back, all these sorts of issues, and I think you may be causing problems in two ways, firstly, missing out what a lot of patients really want but, secondly, restricting it to things where there are a lot more practical difficulties.

Chairman: Which leads neatly to the pathways of care and Baroness Morgan is going to talk about this.

Q298 Baroness Morgan of Huyton: You have both talked about pathways of care in your evidence and, indeed, we have heard quite a bit about this from people who have been at previous sessions. I was going to ask how you think the pathway to care can be assured under this Directive, but actually, having heard what you have said already this morning, I think it is more appropriate to ask: do you think it is possible for a pathway of care to be properly delivered under this Directive with cross-border healthcare?

Dr Meldrum: I am sure it is possible but it is not easy. Without wanting to repeat myself, Vivienne has talked about the cultural difficulties, the language difficulties, even differences in the way that various care pathways are run in different countries; these are not insuperable problems, but they have to be addressed if we are going to maintain patient safety, and so it requires a lot of thought. It may well be that it will be easier with certain countries or with certain places, and one thing might be to almost pilot this in terms of actually not having too many centres where people can have this cross-border treatment but limited to a few where you know that you can look at these issues much more carefully, rather than suddenly opening up to hundreds and hundreds of different potential providers. I know that in itself would cause restrictions, but it might be a safer way to try to develop the system and learn from mistakes in a more controlled way.

Ms Sanderson: There are practical issues for dentistry certainly in pathways of care. It is at both ends. There is the very simple, how do you cope with somebody who has got an infected socket if they have had a tooth extracted. That is at a very early, simple level, but I think more complex than that dentistry is often not a snapshot event. I can give you an example of one of my young patients who has uncontrolled decay, who needs considerable help with his diet, with his cleaning, and with his attitude to his oral health. He took himself abroad and had eight or nine fillings done, and returned to me, and within three months most of those fillings had failed because of recurrent decay. What I would have done, of course, was develop a long-term treatment plan for him to arrest the decay; to sort out the care first, sort out the emergencies and then develop a treatment plan over perhaps a year or more. We would have ended up with a sound mouth. His care has, without doubt, been compromised from that. Snapshot care is very dangerous in dentistry, in primary care dentistry particularly, so it is at both ends of the care pathway.

Q299 Baroness Morgan of Huyton: Do you think therefore that it is an issue, if you were in the position of a patient coming and seeking advice about whether to go outside the UK for treatment, that you would very specifically raise with them as an issue? Presumably, it is not possible for you to have direct contact with the surgeon or the alternative dentist that they are going to?

Ms Sanderson: Often we do not know.

Dr Meldrum: Patients still do value the fact that there is some sort of relationship between the GP and the doctor to whom they are referring. We have talked earlier about the Choice Agenda and when I often go through all this with my patients, at the end they look at me blankly and say, “Who do you think I should go to, Dr Meldrum?” and it is so much better if you know the person, and you have had links with them. You might not know them as a colleague, but you know of patients that have been treated by them, you have had the feedback from them, and you can tell quite bit about their practice.

Q300 Lord Lea of Crondall: Can I ask a supplementary. Being devil’s advocate in a certain way, in the case of dentists presumably it is not unknown for people to want a second opinion. Either they do not think much of the dentist or they have got some idée fixe about what is wrong with their teeth or whatever. Is that any different because that is within London or within Manchester from being in Brussels or somewhere? Presumably in many ways it is different, but are there some protectionist considerations whereby the profession does not like somebody going somewhere else? I am being devil’s advocate here.

Ms Sanderson: Actually, no, I do not think so at the moment. I think dentists are so busy that that actually does not come into it, certainly not within the NHS field. There may be a concern in the private arena that large and complex cases are going abroad,
CROSSBORDER HEALTHCARE: EVIDENCE

11 December 2008

Dr Hamish Meldrum, Professor Vivienne Nathanson,
Mr Susie Sanderson and Ms Linda Wallace

but that is not what we are talking about here, in fact, and they are often the ones that do cause us concern because they come back with difficulties. You will have seen that we did a survey and discovered that half the dentists we had surveyed said that they had had the experience of patients going abroad for care and half of those said that they had had to pick up the pieces when the patients came back again.

Lord Lea of Crondall: What I am trying to get at is whether that is different from somebody saying, “I want to try another dentist,” where you might think that person’s treatment is compromised because he did not trust your treatment and you are not over the moon about that presumably, but that person could run into the same difficulties.

Q301 Chairman: Lord Lea is wanting to know, quite clearly, whether or not it is true of people who travel. Did your survey ask about people going just to other dentists or going abroad and would they have the same problem if they went from London to Manchester?

Ms Sanderson: I do not know the answer. Linda, can you help?

Q302 Chairman: It would be interesting to know whether it is a problem of people going to the person who does not know their condition or whether it is to do with the European dimension, which is what we are interested in.

Ms Sanderson: I am sorry, I heard the word protectionist and I do not think that does come into play with dentistry. I am a practising GDP myself, I do two or three days a week in practice, and it certainly would not occur to me. I would respect a patient’s wishes to get a second opinion absolutely without any question, because it either backs up your own treatment plan or you have lost the patient’s confidence anyway so it does not matter.

Q303 Chairman: It raises an important point which would be useful to know, which is whether or not people going abroad are coming back with more complications than those going to other dentists.

Your survey asked one question and it would be interesting if we had a survey that asked the other.

Professor Nathanson: One of the key issues here is sometimes it is not so much about more complications; it is about different complications. A lot of it is about different ways of treating the same condition, certainly in medicine, and I am sure it is the same in dentistry. If you treat things in a slightly different way, then the normal expectation of complications would be different ones, and that becomes difficult when somebody comes back because these are not complications you would normally see and expect to have to manage. You then may not have someone that you can talk to and say, “Is this a routine complication and what is the normal management of that complication?” if there is a very different tradition of treating a particular problem. I guess a lot of what we are talking about here is surgical, whether it is dental surgical or more general surgical treatments, and that is one of the key issues about why you have to know in detail what the treatment was, so that the people who then have to pick up dealing with the complications are aware of what it is. There are many different models for treating different conditions, and if you have a tradition of treating it in one way, you know what the complications are, and that is where the international perspective is very different. Anywhere in the UK you get very few variations between a standard model.

Chairman: That might lead you nicely into asking about co-operation between Member States because we know that a lot of times we can learn from other people. Certainly when we did the organ donation inquiry we found that we learned a lot from Spain.

Q304 Lord Lea of Crondall: There are a lot of considerations here and the BDA are saying in paragraph 17 of their written evidence that these would be long-term projects. Perhaps someone could just elucidate that. Obviously it is not going to come in tomorrow but, on the other hand, what do you actually have in mind there? The BMA, amongst other things, have mentioned language barriers and differences in structuring and recording of information. All of this raises quite a number of headings under co-operation between Member States. If I might throw in an extra one: do you have cooperation in how to deal with fraud? Will that not become, as it were, a rather important element?

Dr Meldrum: Where to start? Let us start with fraud. The short answer is I do not honestly know what co-operation there is in terms of that type of fraud. I know there has been a lot of work done in the UK to try and reduce fraud, whether it be by health professionals or by patients, but I am not aware of similar activities taking place abroad. I am certainly not aware of what, if any, co-operation exists between Member States in those terms. On the more general points though, we have touched on language, we have touched on culture, and I have mentioned the difference in drugs that might be used. Occasionally I have had patients who have had treatment, particularly in Spain or somewhere, who will come back with drugs of which we do not have a direct equivalent here. There are issues too, although this is partly dealt with in the proposals, about how payment systems should work. Obviously we have a different system in this country as to how patients get drugs and what they pay for them. Of course, the recent debate about top-up payments has added even
more complexity to that as to what a patient is entitled to under the NHS and what they might be expected to pay for themselves, so there will be issues about drugs that may have different arrangements applying to them in the EU and whether patients are still going to receive these entitlements when they come back.

Q305 Lord Lea of Crondall: On fraud, I was not referring to the fact that there may be fraud in France and different sorts of fraud in Britain—hopefully not—but will this whole set-up produce a new sort of fraud?

Dr Meldrum: I am sure there will be entrepreneurial fraudsters who will take advantage of any change. Anything which by nature has a degree of bureaucracy associated with it probably has opportunities for those who want to take advantage of it.

Lord Lea of Crondall: On the language question, we have a colleague who is a very notable interrogator on this Committee, he is not here at the moment, but he is Chairman of the Cheshire Cheese Manufacturers’ Association, so he knows about cows, and he said, “By the way, I don’t need my vet to talk to my cows to make them tell him what is wrong, do I?”

Chairman: I think this is the moment to move on!

Q306 Lord Lea of Crondall: How serious is the language question, in other words?

Professor Nathanson: Language is a major issue. The biggest development in healthcare, and particularly in medicine, is the concentration on communication skills. We rarely practise any form of veterinary medicine. I mean that in the sense that there are occasions where you have a patient who is unconscious and you cannot communicate, and then you might say that you are in the same situation as a vet, but in fact you are not because you are talking to the family, the friends, the neighbour, whoever else, and communication is key. One of the things we have concentrated on is not only doctor-to-patient communication and patient-to-doctor communication but doctor-to-doctor and doctor-to-nurse and so on. It is a very complex set of communications. If you get that right, then it helps ensure patient safety, the quality of care and that the patient journey through healthcare is a good journey. If you get them wrong it can be a disaster.

Dr Meldrum: I was just going to add that your veterinary friend may not talk to the cows, but he will talk to the farmers!

Q307 Chairman: Does anyone want to add anything?

Ms Wallace: I think in relation to fraud, no, I do not think we have anything to add on that. In relation to e-health however, we think that it is not particularly far advanced in dentistry, again with most dentistry being delivered in family practices. The opportunities for e-health really are relatively undeveloped. There will be some centres of excellence of course outside the primary care sector, but that is why.

Chairman: Can we move on to Lord Cotter and fitness to practise.

Q308 Lord Cotter: There is another aspect of cooperation there, the eligibility of professionals to practise. How do you think the exchange of fitness to practise information should be addressed in the draft Directive and what do you think would be the implication if such information were not included?

Dr Meldrum: I am happy to start on this. I think there should be exchange. At the moment the situation is that any doctor who is registered within their own country in the EU has a right to practise in any other EU country. There are two issues. First, the systems of regulation in different EU countries differ quite considerably. As you know, we are bringing in a system of revalidation which includes relicensing in the UK, which is well in advance of almost all other EU countries, so there will slightly different standards for being assessed as being fit to practise in the UK compared with what there will be in other EU countries, but we will still have to recognise others. The second area is where there are concerns or there have been findings against doctors, then we would expect very free exchange. It is essential that that exchange of information does take place between EU countries. At the moment I think it is still quite patchy as to how easy it is to find out whether there have been any problems with the registration of a doctor from another country.

Ms Sanderson: I can echo that. The General Dental Council at the moment is tussling with how to make sure that all dentists are validated and revalidated to be fit to practise, so that is very much a topic on the agenda. We understand that there will be a Green Paper on mobility of professionals emerging from the Commission soon, so we hope that that will give us an opportunity to discuss that with the Commission as well and address that side of the issue. We do need some clarity; it really is very important.

Chairman: That takes us neatly into redress when things go wrong.

Lord Kirkwood of Kirkhope: I have a couple of questions about redress and legal matters, but just as a matter of curiosity—and I think the answer to this question is a number—on a scale of one to ten, how enthusiastic are your members about this, if zero is really not very enthusiastic and ten is very enthusiastic? I am listening to you carefully, watching...
your body language and looking at the evidence, and the principle is accepted and the principle is hard to contradict.

Baroness Morgan of Huyton: If I could add to that, how aware are they of the discussion at all?

Q309 Lord Kirkwood of Kirkhope: Indeed that, because there must come a point where with the qualifications and the stuff you need to put in to make it all work it is not worth doing. It is not a trick question.
Dr Meldrum: My guess—and it is very much a guess, partly because I think there is a lack of knowledge, and that is something that we will have to address—I would think that it is around about three or four on your scale.

Q310 Lord Kirkwood of Kirkhope: That is what I thought. And the dentists?
Ms Sanderson: I think most of them do not know it is happening. They are irritated when they have to pick up the pieces, and we have had that debate already, so they know that patients can go abroad to have care, and they know that the undue delay clause has been there for a while in the Watts case, but I do not think they are interested at the moment. They are too busy. Is that fair?
Ms Wallace: Yes.

Q311 Lord Kirkwood of Kirkhope: That is significant in itself really. Thank you for that. Let me ask you two quick questions because this gets more complicated the more you get into it. I used to be in favour of it! What is regulatory redress? I was a provincial lawyer in a previous existence and I know what compensation and redress mean, but what does regulatory redress mean, in six sentences, or in one, and that is addressed I guess to the BMA?
Professor Nathanson: We believe quite simply that a patient should be able to lodge a complaint against a doctor who has caused them unnecessary harm wherever that doctor is practising.

Q312 Lord Kirkwood of Kirkhope: Is that not a normal part of the financial compensation plan?
Professor Nathanson: Indeed, but we are just saying that it needs to be sorted out at the same time as all the other management arrangements so that you do not have a patient who goes to another country, and who comes back having had unnecessary harm, and they are then faced with the fact that nobody is able to advise them on how to get redress against the doctor in that other country. We are just saying that we need to be fair to patients so that they are not put off going if they are otherwise enthusiastic, because they are aware that there could be risks, by the fact they have no idea whether they would ever be able to get compensation or, even worse, that they come back having not thought about that, having been harmed, having had truly bad care, and unable to get compensation because nobody knows how to do it.
All we are really saying is that part of the bureaucratic process needs to be absolute clarity that redress can happen across the international boundaries, and how that is done should be a clear part of the information available for patients. Some patients find it difficult to know how to get redress against the NHS, which is appalling, but it still happens.

Q313 Lord Kirkwood of Kirkhope: That is an omission, as you see it, at the moment? Your evidence clearly points to that.
Professor Nathanson: We would want to see that.

Q314 Lord Kirkwood of Kirkhope: And you would know what you would need to put into that to make it right?
Professor Nathanson: More or less, yes.

Q315 Lord Kirkwood of Kirkhope: Thank you for that. I do not think that applies directly to the dentists, or maybe it does?
Ms Sanderson: Well, something that is very uppermost in dentists’ minds is the requirement as part of the clinical governance agenda to whistle-blow if you are concerned about a colleague or a colleague’s skills or a patient safety issue. Certainly it is not just dentists, it is the dental team as well who are now regulated by the General Dental Council. The whole team has an obligation to whistle-blow if they are concerned. That has been a very, very difficult agenda to pursue, as you can imagine, because we do not do that sort of thing. “There but for the grace of God go I,” you quite often think. If you are doing it in one Member State you would imagine that this ought to be possible throughout the whole of the European Union.

Q316 Lord Kirkwood of Kirkhope: In Romania?
Ms Sanderson: It comes back to regulatory redress. It is not just the patient that should be making that sort of comment to the home regulator, but perhaps the receiving practitioner in the home country who has had to pick up the pieces should also have an obligation. I merely question it as part of the clinical governance agenda.

Q317 Lord Kirkwood of Kirkhope: That is understood and that is very helpful. Just finally from me on the legal and regulatory side, I think people understand what E112 stands for because it is an established procedure and process. We are learning that there could be a potential conflict. This is not
something that would naturally have occurred to me, I have to say, between our cross-border healthcare move and an E112 situation. Is this something that we should worry about? Is there a conflict there? If there is, who is the referee? How do we sort that out? Is there a system of appeal? And a whole series of other questions which I have not got the stamina to ask you!

Professor Nathanson: I think we would agree with you that there is confusion and there needs to be clarity. The question really is can you draw enough of a distinction between the two situations, E112 being about the delaying factors, and if the more general Cross-Border Healthcare Directive is about everybody having a right with relatively few caveats, then one could argue that both will work, but when you start to say that you have prior approval potentially for cross-border healthcare, then you need to say that is for general healthcare and then there will be E112, which is about what is undue delay. When we consider that some of the debate has been about what constitutes unreasonable delay, if you are a patient in pain or if you are a patient in fear, then any delay is undue. All of those caveats come in. I think it could be incredibly difficult to ensure absolute clarity and it may be that, in fact, the E112 route may disappear if the Cross-Border Healthcare Directive is drawn sufficiently broadly.

Q318 Lord Kirkwood of Kirkhope: So that might be an avenue of resolving this potential conflict? Professor Nathanson: Indeed, provided that there is reasonable equity in the way that it is applied around the UK, and that is why again a UK-wide system rather than a local PCT system would work.

Q319 Lord Kirkwood of Kirkhope: Is that something that you would positively advocate? Professor Nathanson: We would advocate anything that gave absolute clarity, and I think it is as simple as that.

Q320 Baroness Morgan of Huyton: I was really interested in the BMA evidence on standards of care and the fact that you thought a set of minimum quality standards would be beneficial, because that was in contrast to what the GMC said, who really argued that minimum standards would tend to lower the quality rather than raise it. We would really like to know more about why you think this would be beneficial. I do not know if the BDA also have views on this. Professor Nathanson: Yes, we believe that a minimum standard could be beneficial but only provided you start off at the highest standard. There is the big caveat there. The GMC is absolutely right that there is always a danger when you put in minimum standards that you start off at the lowest common denominator. We would not want that; we would want either the very highest or very close to the very highest standard. That is where having an EU-wide policy could help. It could help in the areas of the UK in which we are relatively weak to raise our standards and it could help all over Europe to say we should all be trying to operate at these higher standards. That is obviously in the interests of patient care and patient safety because it is all about quality standards. That is why we would like to see it, but we would put in that big caveat.

Dr Meldrum: It really gets back to what I was saying earlier about having common data sets that are reproducible, comparable and meaningful. Yes, I would agree that the minimum should be quite high.

Q321 Baroness Morgan of Huyton: How would they be drawn up and who would draw those up? Professor Nathanson: I think that is a matter for healthcare professionals, patients’ groups, regulators, governments, the people who set standards in their own countries, to get together and say how can we make sure we understand what the standards are. Some of those that are different are different because of the processes and the ways in which we describe care, but what is not beyond us is actually coming up with something that is pretty close to the top level of care, and that is a common understanding. The other advantage of working through it in that way is that there would be genuine discussion about how we measure standards, how we measure outcomes, even how we measure outputs, and that would have the advantage of giving better understanding, and would actually feed into the national data sets of what we do because it would mean that they were described in the same way with a commonality which would make it easier for people from any country to judge whether the care offered in place A was something that they wanted.

Q322 Chairman: Can I ask you a precise question on that and that is whether you actually have a view on the definition of “harm” as it stands in the Directive? The Directive says that harm means “adverse outcomes or injuries stemming from the provision of healthcare”. You may want to think about that and let us know what you think. We have to get you to tell us what you think; we cannot have a view of our own. We are quite interested to know whether you would have a view on that definition of harm, which we did not think of asking you in advance. Dr Meldrum: I am happy to get back to you. At first sound, that does not sound too bad a definition, but we will get back to you.

Ms Sanderson: Yes, I could use that definition but we will debate it as well.
Chairman: Lady Morgan, do you have anything else?
Baroness Morgan of Huyton: No thank you.

Q323 Chairman: The other issue about working together is about liaison between representative bodies across the EU, something Lord Lea is particularly interested in, having been himself involved in it. As representatives of doctors and dentists, to what extent do you liaise with your counterparts in other EU Member States? Do you have a collective European body representing the service providers from across the EU? Are you aware of their views on the Directive? If so, how do those views compare to your own? Shall we start with the dentists this time?
Ms Sanderson: Yes, we do have a very active body called the Council of European Dentists, and in fact it met about ten days ago. This Directive was debated at length, as you can imagine, and there is a working group which is pulling together some suggested amendments. In fact, on CED’s behalf, and also on the BDA’s behalf, I met with the rapporteur for this Directive a couple of weeks ago, and talked through with him his views on how this is going to be implemented, and that was very interesting indeed.

Q324 Chairman: In what way was it interesting?
Ms Sanderson: My earlier comments about the interpretation of why “prior authorisation” is useful came from my discussion with him. I had assumed that it was clinical prior authorisation in terms of a referral. He is much more focused, for example, on enabling patients equity to be able to seek treatment abroad without having the burden of the patient charge getting in the way, so that was just one interesting thing. He is also very keen on quality standards and he is also very keen on league tables, and that was the point at which we departed on our agreement, I am afraid. League tables are misleading and difficult and so we did not agree about that. It was an interesting debate and it informed the CED debate a few days later as well.
Dr Meldrum: Similarly, there is a standing committee of the European Doctors, CPME, and it has branches underneath it representing specialists, GPs and junior doctors. Unfortunately, it is not quite such a happy situation in that recently the French, Italians and Spanish have all pulled out of that group, for a variety of reasons, which would take too long to go into, but it is in some trouble at the moment. We actually chair the group at the moment. I do not think it is anything to do with the fact that these various people have left, but there are some problems. We still do liaise quite closely with our European counterparts and, funny enough, on the general practitioner side, the relationships seem much better and there is more happiness and light there. We also have an office in Brussels, one girl, but she is very good, so we do have a lot of links with Europe. As to what European colleagues think, I think on Lord Kirkwood’s scale they might be about six, or perhaps seven, in that I think they see, because of the ease of transfer across borders for other things, that this is more like it. Also, most of the European countries run a sort of social insurance scheme rather than our NHS scheme, which again in practical terms probably makes it a bit easier. If you can get your insurer’s permission, then you are all right, and they are used to paying first and then claiming back afterwards, which is not what UK citizens would do. I think they are slightly more supportive although they, again, see some of the practical issues.

Q325 Chairman: Do you have a view on the two schemes that exist in this country in terms of looking after practitioners and whether one is more advantageous than the other?
Dr Meldrum: The two healthcare schemes? I still believe fundamentally that both the most efficient, least bureaucratic and fairest way is to pay for the NHS out of general taxation, which is on people’s ability to pay, rather than going down the complexity and to some extent the unfairness of a state insurance scheme. That has always been the BMA’s view.

Q326 Lord Lea of Crondall: Could I ask what generally this European body, in either of your cases, would actually be doing in an average year without this initiative coming from the Commission? One classic piece of Brussels politics of course being that if you do not want legislation and bureaucracy, what about doing some benchmarking of your own. You say there is one girl working there, which means she is 15 years old presumably! Seriously, is there any alternative aspiration to doing a bit more work together?
Professor Nathanson: In terms of our European office it is one young woman. She is in her late 20s and has been there for two years.
Dr Meldrum: I should not have called her a girl.

Q327 Baroness Morgan of Huyton: You are going to be in trouble when you get back.
Professor Nathanson: And she is a Liverpudlian like me.
Dr Meldrum: And she is formidable.

Q328 Lord Kirkwood of Kirkhope: We will not tell her!
Professor Nathanson: I think what happens at the Standing Committee of European Doctors and at the other sub-groups is a lot of work on co-operation and talking about things like benchmarking and how we raise standards. For years the CPME has been about
common standards of training, about recognition of diplomas and what a higher diploma is and what a consultant senior diploma means, and how we make sure that every country puts it in place in a way that other countries should recognise, because it actually is a marker of the quality of training, and all that being about the patient safety element. Indeed, at the moment, one of the big debates (which will continue and I do not see it ever finishing in Europe) is what is a speciality, because some parts of Europe recognise some elements of medicine as a speciality and others do not. I am trying to remember which ones. For example, plastic surgery has not been recognised everywhere. Things like that actually become extraordinarily important because if you have somebody holding a consultant post or the equivalent, however that is described, in different parts of Europe, it is only if you actually know what a common standard is that you can allow free movement of doctors, which is good, and we want to encourage free movement of doctors, because that means that you share the best ideas. A lot of it is based upon how you improve the quality of care that patients get, and how you ensure that doctors get the most possible support and help and assistance in learning from colleagues all over the world so that they can change their practice and improve it for the sake of patients.

Q329 Chairman: We have come to the end of our time. I have found it, as has the Committee, extremely valuable. You have elucidated a number of points that we need to get into our report. As I say, we have to get you to tell us these things as witnesses and you have done very well this morning. Thank you very much indeed for coming. Dr Meldrum: Thank you and I hope everybody recovers as quickly as possible!

Supplementary memorandum by the British Dental Association

Our view is that the definition of “harm” as included in the draft directive is workable, but our concern is that it should be taken to be “proven” harm. In other words, the onus should remain with the patient to prove that harm has been done, rather than on the health professional to prove that their actions did not do harm. This is something that has arisen before in Europe, when some MEPs were keen to reverse the burden of proof. It is impossible to prove a negative in these circumstances. If it were to be presumed that the health professional did harm unless they could demonstrate otherwise, and that the patient should be compensated regardless, there would have to be a centrally-funded no-fault compensation of some time.

December 2008

Supplementary memorandum by the British Medical Association

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

Thank you for the opportunity to appear as witnesses for the Committee’s inquiry into cross-border healthcare. We provide further information below following the Committee’s request for the BMA’s view on the Commission’s definition of harm. We would also like to draw the Committee’s attention to a further concern from the BMA regarding telemedicine.

DEFINITION OF HARM

The definition of harm in the context of unexpected adverse outcomes from medical treatment is a complicated legal matter and the BMA would advise policy makers to examine previous legal definitions in British case law on medical negligence and causation. In the context of the European Commission proposal, the BMA would support an amendment which would clarify that harm is defined as “Avoidable adverse outcomes or injuries stemming from the provision of healthcare”.

Ideally, the BMA would welcome the introduction of a no-fault compensation system which would cover “no-fault harms” that are not related to poor quality or inappropriate care. The redress that the BMA has called for in its original evidence relates specifically to types of harm where there is a “fault”.

Supplementary memorandum by the British Medical Association

December 2008
Telemedicine

The BMA is concerned that the article (16) on e-Health in the draft directive does not offer adequate protection for patients. The BMA calls for the regulation of telemedicine to be mentioned explicitly in this article. The BMA calls for doctors who undertake cross-border telemedicine and teleradiology to have the equivalent regulatory requirement to practitioners in the country where the patient accesses healthcare.

December 2008
INTRODUCTION

1. UNISON is the major trade union in the health service and the largest public sector union in the UK. We represent more than 450,000 healthcare staff employed in the NHS, and by private contractors, the voluntary sector and general practitioners. There is also a wider interest in the NHS among our total membership of more than 1.3 million people who use, or have family members who use, health services. UNISON is a member of the European federation of Public Service Unions (EPSU) and welcomes the chance to respond to this inquiry, having already responded to the European Commission’s own consultation on community action on health services in 2007. Given the space restrictions, our response is limited to the main areas of concern for the union, many of which relate directly to the specific questions laid out in the Committee’s inquiry.

MARKETS

2. At the root of UNISON’s objections to the Commission’s Directive is the fact that throughout its recent dealings on healthcare, the Commission has not merely been seeking to address the rights of patients, but using the exercise to increase the use of market mechanisms in European healthcare—particularly since health services were excluded from the Services Directive in 2006. For example, the June 2006 statement by the health ministers of the EU was explicit in revealing “increasing interest in the question of the role of market mechanisms (including competitive pressure) in the management of health systems”. The legal basis under which the Directive has been introduced is Article 95 of the Treaties, which relates to the establishment and functioning of the internal market, rather than Article 152 which relates to issues of public health.

3. Case law already exists from the European Court of Justice (ECJ) allowing patients to receive care abroad if they wish to do so and existing levels of cross-border healthcare are actually very small: the EU’s own figures confirm that it represents only 1% of public expenditure on healthcare and only 4% of Europeans received medical treatment in another member state when the last yearly survey was conducted. Other forces are at work here. The Directive is explicit in its desire to go beyond merely patients’ rights: Article 1 stating that the Directive “establishes a general framework for the provisions of cross-border healthcare”. There are also repeated references to “the internal market for cross-border healthcare” throughout the Explanatory Memorandum to the Directive.

4. Within the Directive a patient has the right to reimbursement of costs for treatment abroad regardless of the type of provider. This brings up the ugly prospect of the UK’s publicly-funded NHS having to reimburse private providers in foreign countries. It has even been suggested that this could lead to private European health providers being given a place on the NHS Choose and Book system.

1 Council of the European Union, Council conclusions on common values and principles in EU health systems, Annex: statement on common values and principles, 5 June 2006
3 European Commission, Cross-border health services in the EU: analytical report, June 2007, p5
5 Health Service Journal, “Euro providers could claim place on choose and book”, Sally Gainsbury, 10 July 2008
INEQUALITIES

5. A key problem with the use of the market in healthcare, as witnessed in the fledgling UK market system and elsewhere in Europe, is the fact that it encourages healthcare providers to choose to treat the most profitable patients and conditions, but to ignore other more problematic and less profitable ones. Such inequalities would be further entrenched by the practical implementation of the EU directive. To start with, patients would have to pay upfront for cross-border healthcare and then claim it back—something which would only be an option for those with sufficient funds. Secondly, the amount that patients can claim back from the NHS (or any other health system) once they have been abroad only covers what the treatment would have cost in their home country. So if the procedure is actually more expensive abroad the patient pays extra—not something that most patients in the UK or elsewhere will be able to afford, and particularly likely to affect those from countries with relatively low-priced health systems, such as Bulgaria or Latvia. Thirdly, the patient cannot claim back the costs of travel or accommodation for their trip abroad, so must pay this themselves. And finally, the directive does not deal adequately with the question of after-care; whilst a patient’s operation abroad would be covered, their equally important subsequent physiotherapy, for example, would not be. Inequality goes beyond purely monetary factors: on a practical level, travelling to access cross-border healthcare is only an option for those with sufficient physical mobility to travel.

6. All of these shortcomings demonstrate that providing an equitable comprehensive healthcare service is not what lies at the heart of the Directive. All would further entrench healthcare inequalities in the UK—an area in which the government’s healthcare policies have so far made least impact and which was exposed recently by a damning World Healthcare Organization report. Such issues also tie into the ongoing debate in the UK about the use of top-up payments for NHS care. The Mike Richards’ review into this emotive subject will report in October and a key problem that UNISON highlighted in its submission to the review was that allowing an expansion of top-up payments would threaten the NHS founding principles of equity, accessibility and universality. For the reasons outlined above, the EU directive makes the prospect of a wider use of top-up payments much more likely. Those with responsibility for healthcare in the UK must do everything within their power to avoid a situation where healthcare becomes based increasingly on the ability to pay.

7. Where inequality is concerned there is a wider question about inequalities within the EU. In addition to the point above about patients from countries with low-priced health systems, the Commission’s own research demonstrates that it is largely people from the New Member States that cite lack of affordability as the main reason why they would choose not to travel abroad for healthcare. The Directive therefore stands to exacerbate differences between the EU15 and NMS12 member states.

IMPACT ON THE NHS

8. The Directive states that only hospital care (broadly defined as care requiring an overnight stay) would require patients to offer their own health system prior authorisation of their intention to travel for healthcare. This is problematic on a number of levels. To begin with, in terms of subsidiarity, under Article 152 of the Treaties this is clearly a member state issue which brings into question the competence of the EU to legislate in this area. Definitions of hospital and non-hospital care vary from one country to another and the definition of a hospital in itself is open to debate, particularly with new structures such as polyclinics and GP-led health centres coming into being in the UK. Some countries could therefore find themselves with a disproportionate number of patients able to travel for care abroad without seeking prior authorisation.

9. Article 8 (1b) of the Directive does recognise that hospital care might not require an overnight stay, but gives the Commission responsibility for drawing up a list of treatments that this might cover—meaning yet more significant powers for the Commission. Article 8(4) refers to prior authorisation being “limited to what is necessary and proportionate”. This wording allows too much scope for interpretation and past experience from other areas of EU law would indicate that the ECJ will eventually have to decide what “necessary and proportionate” actually mean, forcing the Court to become more involved in defining health policy and thereby exacerbating one of the very problems the Directive was meant to solve.

10. The Commission assumes that it is only cross-border hospital care that would affect the financial sustainability of healthcare systems, which is an outdated approach that shows no appreciation of current initiatives to move care increasingly out of hospital settings and to focus on preventive care. The lack of prior authorisation being needed for non-hospital care would make planning that much harder for health systems and would raise concerns about financial instability; no one wants to see the NHS returning to a situation of deficits, job cuts and closures as we saw in 2006–07. The NHS could be particularly susceptible to this type of planning blight now that more than 85% of the health service budget is administered by PCTs with care

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6 World Health Organization, *Closing the gap in a generation: health equity through the social determinants of health*, September 2008

7 European Commission, *Cross-border health services in the EU: analytical report*, June 2007, pp5, 23
increasingly taking place in the community. Perhaps an even more fundamental issue is the heavy burden of proof placed on member states to demonstrate that prior authorisation is needed, even for hospital care.

11. Problems with planning and financial stability mean it is logical to assume that European governments would want to limit the amount of care that could be accessed abroad without prior authorisation being given. One of the big successes of the UK government’s health policy has been to virtually rid the country of hospital waiting lists and to massively reduce waiting times. This has been achieved in part by boosting the amount of day surgery and limiting overnight stays wherever possible to free bed space. Under the Directive’s definitions some of this activity could potentially be classed as non-hospital care, despite the fact that it does actually take place in a hospital, meaning that patients could travel for a greater amount of treatments without seeking prior authorisation. This could create a perverse incentive for the NHS to cut down on day surgery—thereby increasing waiting lists and waiting times—so that a greater number of procedures remained covered by the need to seek prior authorisation. Similarly, there could be less incentive to pursue the laudable aim of shifting more care out of hospital settings, if this meant fewer prior authorisations needed to be sought.

12. There are further problems ahead for the NHS in the shape of the additional administrative burden the Directive is likely to place upon the health systems of member states. This could take a number of forms: member states will need to set up a national contact point to provide information on cross-border healthcare for home and incoming patients; there are new data collection requirements relating to cross-border healthcare with member states having responsibility for gathering information on how to access care abroad; and when patients come to the UK for care the NHS would need robust systems in place for charging sending countries. In attempting to play down the considerable detrimental impact the Directive would have on health inequalities, the Commission has said that there would be nothing to stop member states from paying the costs of care upfront if they wanted to—an option which would further increase the bureaucratic burden on the NHS.

13. The Directive would force member states to recognise the prescriptions issued by providers in other member states. This means that patients could be prescribed medicines which are not even available in their home country. If a particular product has been authorised to be marketed within a member state and a patient arrives with a prescription for this product from elsewhere then the NHS would be required to pay for it. The Nursing and Midwifery Council has also called for clarification about whether the Directive will compel the relevant authorities in other member states to recognise prescriptions signed by UK nurses and midwives, as the UK is among only a small number of EU countries to train nurse and midwife prescribers.8

OTHER ISSUES

14. The Directive’s approach to redress and professional liability is too simplistic. The Directive assumes that the health professional should always be the culpable party where remedies and compensation are concerned. This does not take into account, for example, the building or conditions in which the worker is providing services, which could have an equally important bearing on serious incidents taking place. There is also inadequate consideration of how compensation procedures would operate in a cross-border situation, which could lead to lengthy, complicated and expensive legal procedures becoming the norm.

15. Article 16 of the Directive concerns e-health and refers to “achieving the interoperability of information and communication technology systems in the healthcare field”. The Directive also calls for the interoperability of ePrescriptions. Both proposals are totally unrealistic, as anyone familiar with the huge problems encountered in the UK with merely trying to establish the interoperability of health IT systems in one country can testify. It has recently been revealed that a number of London hospitals are considering legal action due to the poor performance of new systems under the NHS National Programme for IT9 and the NHS is apparently facing a £700 million legal action from Fujitsu over a failed NHS IT project.

16. The Directive is a regressive move where models of healthcare delivery are concerned. It only considers services provided by health professionals from one of the regulated professions, with a strict distinction between medical and non-medical care. Countries such as the UK are attempting to move beyond this old-fashioned dichotomy by favouring a more holistic approach to care in which social, psychological and other aspects are integrated with the physical care provided.

17. It is also worth commenting on what is omitted from the Directive. Whilst purporting to be about the rights of patients, the Directive fails to address the basic right of European citizens to access high quality healthcare. The Commission has missed the chance to provide a truly patient-centred approach to the health of millions of Europeans.

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8 Nursing and Midwifery Council, “NMC responds to EU directive on cross-border healthcare, UK”, 4 July 2008
CONCLUSION

18. UNISON believes that far from its stated desire of reducing inequality, the Directive would do precisely the opposite as it seeks to further the expansion of European healthcare markets under the guise of boosting patient choice. Furthermore, the Directive is unrealistic and if implemented would have a detrimental impact on the NHS. The Directive is also a missed opportunity to assert the fundamental right of patients to receive healthcare within Europe.

September 2008

Memorandum by Unite

This response is submitted by Unite the Union. Unite is the UK’s largest trade union with two million members across the private and public sectors. The union’s members work in a range of industries including manufacturing, financial services, print, media, construction and not for profit sectors, local government, education and the health service.

Unite is the third largest trade union in the National Health Service and represents approximately 100,000 health sector workers. This includes seven professional associations—the Community Practitioners and Health Visitors’ Association (CPHVA), Guild of Healthcare Pharmacists (GHP), Medical Practitioners Union (MPU), Society of Sexual Health Advisors (SSHA), Hospital Physicists Association (HPA), College of Health care Chaplains (CHCC) and the Mental Health Nurses Association (MNHA)—and members in occupations such as allied health professions, health care science, family of psychology, counsellors and psychotherapists, the family of dental professions, audiology, optometrists, opticians, estates and maintenance, ancillary and ambulance workers.

INTRODUCTION

1. Unite believes the Healthcare Directive published by the European Commission on 2 July 2008 aims to create an EU single market in healthcare services.

2. The initial reasoning for the Directive was that it was needed to clarify EU legislation in the wake of the Watts decision and the ruling that people could seek treatment abroad in instances of “undue delay”. Unite fears the opportunity has been taken by the European Commission to try and create an EU internal market in healthcare. Although presented as strengthening patients’ rights by enshrining the right to choose where to be treated, the definition of “cross-border healthcare” in the Directive goes much further than simply enshrining a right to patient mobility. The published Directive also includes allowing cross-border provision and provides for the movement of healthcare professionals across the EU.

IMPACT OF THE DIRECTIVE

3. The European Public Services Union (to which Unite is affiliated) has stated that “The definition of cross-border healthcare, particularly the right to provide a healthcare service from one member state to another, opens up to questions the issues of quality control, adequate safety monitoring and transparent adherence to agreed standards. The net result is to make healthcare provision easier for private actors to become involved, and harder to monitor quality.”

4. The European Commission has stated that “It is better to specialise in certain things and rely on your neighbour for something else and vice versa”. This ignores that only 1% of patients express a desire to take advantage of a medical service abroad. The vast majority of patients prefer to receive healthcare close to their own locality, language, family and friends.

5. Despite being couched in terms of patients’ mobility the proposal will only benefit those who have financial means to pay for travel and accommodation. The Commission proposals would allow patients to travel to Member States for operations where they would pay up-front. Their “home” health service would then reimburse the cost to an agreed level for each operation. This would allow those who can afford the operating and travel costs to have their procedure fast-tracked in the destination country.

6. The proposals have a clear administrative, legal and bureaucracy cost associated with them that is a waste of resources.

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10 EPSU Press briefing, “EPSU reaction to the European Commission EU directive on Cross-Border Healthcare: 10 points that highlight that European Commission has got it wrong on healthcare”, July 2008

11 EPSU Press briefing, “EPSU reaction to the European Commission EU directive on Cross-Border Healthcare: 10 points that highlight that European Commission has got it wrong on healthcare”, July 2008
7. The Commission argues that the failure of a patient to gain prior approval before seeking treatment abroad is not a basis for refusing to reimburse costs. Unite believe this undermines the ability of national governments to plan the funding of healthcare systems. The Department of Health has stated that it is committed to retaining the right of the NHS to decide what it funds.

8. The proposal would allow important powers to be given over to the Commission—in particular, the power to define hospital care in all EU member states. The document states that: “...power should be conferred on the Commission to define for the purposes of this Directive a list of treatments, other than those requiring overnight accommodation, to be subject to the same regime as hospital care”. This directly contradicts Article 152 of the EU treaty that the EU “fully respect[s] the responsibilities of the Member States for the organisation and delivery of health services and medical care”.

9. Unite believes the UK government needs to ensure that decision making powers on healthcare services, and how the funding of national healthcare systems across the EU remains democratic and at a national level. Unite is concerned that if implemented in its current form, the European Commission Healthcare Directive may have a detrimental impact on the NHS in the future.

10. Unite would be happy to discuss any of the points raised in this submission with the Committee further.

26 September 2008

Examination of Witnesses

Witnesses: Ms Karen Hutchinson Reay, National Officer for Health, Unite and Ms Karen Jennings, National Secretary, Health, UNISON, examined.

Q330 Chairman: Thank you very much for coming and welcome. We are very pleased that you have spared the time to come and talk to us about what we think is a very important inquiry. If you want at the end of the session to send us supplementary evidence to amplify any point, if we do not get through everything, please feel free to do so. I am going to ask the witness from Unite, followed by the witness from UNISON, to start by stating your name and official title.

Ms Hutchinson Reay: My name is Karen Hutchinson Reay; I am the National Officer for Health for Unite, the union.

Ms Jennings: My name is Karen Jennings, and I am the National Secretary for Health in UNISON.

Q331 Chairman: Can I ask if you want to make a short opening statement before we begin?

Ms Jennings: Yes, Unite and UNISON come from a very similar perspective on this, and so we have agreed that I will make an opening statement and we would be very happy to support each other in your questions, if you are happy for us to proceed like that.

Q332 Chairman: That would be very helpful.

Ms Jennings: My Lord Chairman, we are also very pleased to be invited to give evidence to what we consider to be an extremely important issue. We believe, if I may use unparliamentary language, that this Directive is a bit of a dog’s dinner and, therefore, in relation to the questions that you have set, we are concerned that we will be approaching this as though we want this to be amended and we think this needs to be fundamentally challenged. We will illuminate on that further in your questions, but to say that the reason for this is to prevent any further European Union Court of Justice decisions beggars belief. We do believe that this is rather a sledge hammer to crack a nut. If you consider the hundreds of millions of people that live in the European Union and there have only ever been four challenges, this does seem to be slightly over the top. In addition, it is only one per cent of the population of Europe that actually does seek to have cross-border healthcare at the moment. So we are concerned about the haste and the speed of this Directive; we recognise that there is a vacuum in terms of developing legislation across Europe; but we would like to see a proper debate and a much better drafting of the Directive before we proceed on this. Thank you.

Q333 Chairman: I am sorry that one of our members, Lord Wade is not here, because he would be saying to you, I think, what size and why we are doing it. We are where we are, and one of the important things is for us to get the evidence as clearly as we can to the Commission. The Commission do state that their overall aim is to establish a general framework for safe, high quality and efficient cross-border healthcare and they think that this Directive has been needed for much longer than just because of the four judicial decisions. I know that you have real worries about the way this will create a single market in relation to healthcare—that is one of the things you say in your evidence—and, in the light of your comments about the Directive, extending beyond the matter of patients’ rights, I know that you said you would not want to see the proposal changed but rather fundamentally reviewed, but you need to tell us what that means: because if you do not give us the evidence of the
impact, we will not be able to include it in any way in our inquiry. Could you actually take that forward? 

**Ms Hutchinson Reay:** Looking at it from the perspective of patients’ rights, the Directive is based round the notion of increasing choice for what we believe is a small proportion of Europe’s citizens and, effectively, creates an elite access to healthcare rather than developing clinical governance. As Karen has stated, we do agree on this: we do not believe that the Directive is about patients’ rights. The only patient’s right mentioned in this Directive is the right to reimbursement rather than to high quality healthcare near their home. Unite believe the focus of the Directive should be narrowed to reduce the impact on the NHS and to maintain healthcare as an issue that is dealt with at a national level by elected governments. EPSU¹, which I am sure you are aware is the European union that we are all affiliated to, looks to widen the high standards that governments should aim for in their provision of services, but how they organise these services should not be decided at a European level. The impact of implementing the Directive as it stands: Unite, alongside EPSU do not share the Commission’s point of view that a free choice market system where providers across Europe compete for paying and/or insured patients would lead to the best outcomes for all. The Directive is being introduced under Article 95 of the European Treaty, which states as its objective the application of the internal market. Alternatively, it could be introduced under Article 152, which is the public health, or Article 16, of general interest. In equitable access to healthcare services, only those relatively well off enough will be able to take up these rights and the negative impact on the planning and funding of national healthcare systems would be absolutely detrimental to the NHS. Additionally, not all healthcare costs can be expressed through invoicing if holistic approaches to patients’ health are to be taken.

**Q334 Chairman:** One of the issues we have been pursuing is that this is a framework directive and the issues are actually in the detail. That is what you are actually illustrating in what you are saying. However, you seem to give a view that you are fundamentally opposed to the principle of healthcare interrelationships in Europe, and I have to say that John Bowis, who I would not describe as a right-wing politician, really, in the sense of his social care, takes the view that it would be beneficial. Have you talked to other people about how the framework might actually help and what difference you could make: if we could change what is within the framework in terms of the detail, how it could take us forward?

**Ms Jennings:** We have been in dialogue with a number of organisations across Europe on this, and I am President of the European Public Services Union’s Health and Social Services Committee and in that role I am also co-Chair of the Social Dialogue Committee with HOSPEEM, which is the employers’ organisation for hospitals across Europe, and they support our view that this Directive is unworkable and also would create a two-tier system based on the fact that you have to pay upfront and then have to pay the difference, and, of course, that would impact directly in relation to the founding principles of the NHS, but also I think that we are concerned that this Directive is more than a framework, and that is because of the system in which pre-authorisation would be developed through a committee which has virtually no transparency and, therefore, is beyond the reach of public interest. So, for a whole range of reasons, we believe that this Directive interferes in subsidiarity and also gives greater powers to the Commission, which was never intended. So, on a number of levels, one in creating a two-tier system, in developing additional powers and also, we believe, because it is so ambiguous, the framework, that it could lead to further legal challenges in Europe but certainly I think we would have national challenges here in the UK where there were decisions to prevent prior authorisation, similar legal challenges that we had, for example, to the top up of medicines where pharmaceutical companies were supporting charities and individuals in taking forward their legal claims. So I think it could become extremely complex and costly to the NHS.

**Chairman:** Could I bring in Lord Lea’s question next, because I think your question will follow that too and I do think the prior authorisation question has now been raised.

**Q335 Lord Lea of Crondall:** Thank you very much and thank you to both of you for your very useful evidence. We know that you have fundamental objections, but we have two jobs to do: one is to look at the fundamentals and the other is to look at some of the detail. I think you understand that. We would like your view on the proposed system of prior authorisation and the exclusion of non-hospital care from this system and then whether you consider that a case can be made for including all types of cross-border treatment in the provision of a system of prior authorisation. Perhaps I can give you a hypothetical example. Let me take a hypothetical case that I have scribbled out here. A dentist refers you under the NHS to a surgeon for root canal treatment. The UK surgeon says it will cost you £900. You say you cannot afford that. Can you then contact a surgeon in Poland or Hungary and have that treatment having gained prior authorisation for the expenditure from your local NHS? That is opening up a can of worms,
but can you see how you think it would all work in practice?

Ms Jennings: This is an area that we are deeply concerned about. Just coming to the piece of the question in which you referred to non-hospital care, there are so many elephant traps in this particular area because, as the NHS moves towards primary care and moves away from hospital care, increasingly we will be opening up our services to a saturation point, potentially, for those coming across to seek care. For example, cataract treatment is day care now. Therefore, you will not need prior authorisation for that. If you think about even kidney dialysis, if you look at University College Hospital in London, rather than keep patients overnight, what they do is bring them in for a full day’s dialysis and then book them into the hotel across the street. It is much cheaper than keeping them in. Are they day care patients? Are they hospital patients? Under the European definition they would not be hospital patients and, therefore, you could find yourself as a country having patients seeking care in another country and really that country creating a system whereby it is not defined as hospital care and you will be opening up all sorts of concerns around the aftercare of those patients as well, and that is a real concern to us: what happens when somebody has gone abroad, without prior authorisation, without using the proper gate-keeping processes that we have in this country. That is a real, serious concern. We also know from our colleagues in EPSU that there is a real concern, for example, in some countries where they have well-equipped healthcare services but much cheaper than here, and they are concerned that their system of healthcare will become saturated with incoming patients who will be making use of their services over and above what is available to them. Also, there is the issue in many countries that are moving towards moving towards the European country where there are under-the-table-payments going on, and all of that, I think, needs to be explored before we really go down this road of leaving the Commission to decide what needs prior authorisation and this laissez faire approach to day care or non-hospital care.

Q336 Lord Inglewood: I hope I am not unfairly parodying the argument you have given us, but you are coming at it from a very particular perspective. You do not seem, it seems to me, to recognise that we are living in the world of the single market and we are living in a world where, in particular, this private care is now done on a European-wide basis, but I sense you just do not like it. You may well be right in not liking it, but surely one has got to start from the perspective that this is part of the single market, it is part of the wider public procurement arrangements that are coming into place in the world we know across Europe, and it is not really true, is it, to say this is deciding healthcare matters at EU level. What it is doing is setting a framework within which there is considerably increased flexibility for the way in which the Member States can deliver their health services. In particular, you said that only about one per cent of the European population have availed themselves of transnational health provision. Is that not an enormously strong piece of evidence of the fact that something needs to be done? Surely the position we are in is that we have signed up to the European Union, we have signed up to the single market, the doctrine and the supremacy of European law applies and what we have to try and do is to adapt the arrangements we use in our country in the ways that we deliver them to deal with the world into which we are moving. You are right, it poses enormous numbers of technical nuts and bolts problems for the delivery of healthcare which is done in completely different ways in different countries, but if we do not approach this with an can do basis (and, I must say, I thought it was very absent from your remarks, any evidence of approaching it on a can do basis), you never get anywhere in this world?

Ms Hutchinson Reay: I have taken on board what you have said. We have spent hours on this trying to find some positive aspects to it and a way forward on how, because the questions that were put to us from this committee, we have looked at them and tried to find ways forward, looking at it objectively. However, this one thing, following on from what Karen says, is about the individual patients. This is a Directive about patients’ rights. Both Karen and I have been practitioners in our past lives for an awfully long time and, looking at Lord Darzi and the NHS and where we are moving to, none of this fits with the Directive—it is not comparable with the objectives of Lord Darzi and about the patient’s pathway of care. We have episodes of care. We do not have a procurement of one hip replacement, it is very much more of an holistic view, and it is aftercare, and we have grave concerns about what happens to the aftercare of our patients travelling abroad. What about somebody who has more than one medical illness? Again, we have elderly people in the country that have certainly many more chronic illnesses, and for those people it would be impossible to travel, let alone possible to get any insurance. If you look at it from the perspective of an individual and their family, we cannot find a positive in it and we have very much tried to, have we not?

Q337 Lord Inglewood: It is not mandatory, all of this. There is no compulsion on anybody to take healthcare anywhere else in Europe.

Ms Jennings: If I may respond in terms of healthcare being part of the internal market. We successfully fought for healthcare to be excluded from the remit...
of the Services Directive and that was to prevent healthcare becoming part of the internal market.

Q338 Lord Inglewood: With respect, you took it outside the scope of the Directive. It still falls within the scope of the single market. That is the point of this Directive, is it not?
Ms Jennings: But there is a whole range of articles which are quite clear that healthcare is a matter of subsidiarity, and much of what has been recommended in these proposals seeks to undermine that and certainly will impact on the NHS’s founding principles, the system by which we ensure universality and equality of treatment for all, and that is the basis of where we are coming from on this.
Chairman: We have these two important perspectives. One of the things the committee has to do is to look at some of the detail and to raise the questions so that if there is a directive it actually is in the best interests of patients. One of the issues that has really concerned us is provision of information, and Lady Neuberger is going to take us through that.

Q339 Baroness Neuberger: I want to declare an interest. I am a director of Voluntary Health Insurance, a semi-state provider of health insurance in the Irish Republic, which is particularly germane to this, because of the cross-border things that happen all the time across the border in Ireland. I think that is also true between Belgium and the Netherlands, that on the border areas there is quite a lot of cross-border, and in Eastern Europe. So I think what we have to say is, it is here, and Ireland is the one I know and I think there is a huge issue which is about how you provide information which, if everybody speaks the same language and has the same sort of expectations of healthcare, is not that difficult, but as soon as you have very different expectations and you come from a very different system, you have pointed out what some of the difficulties are, but I think there is an issue about who provides the information and how do you make sure that the information is, if you like, translatable in principle as opposed to in language between different states? What do you think are the advantages and the drawbacks of the system that they are proposing of the national contact points?
Ms Jennings: Thank you for that question. It is something that we would like to respond to because, again, I think this is an area where this has not been thought through enough. The contact point they talk about is ill-defined. In addition to that, because the information that is being provided has to be unbiased, there is a potential for it really to be a point of contact, which means that you have got to navigate still further. It is not like the NHS where we have got a list of high-performing hospitals or those that are not meeting the Health Commission’s standards, and so on, and so I think that what we will be left with is something that is quite meaningless, something that if you are articulate, speak other languages, know how to navigate a web-based system, or whatever, you might do well under it, but then you are catering primarily to those that potentially could afford to do this and reimburse for care that they might seek which might cost more. We have also got concerns about IT. As you know, the NHS has been trying to set up an IT system, which has cost an awful lot of money, which is not compatible, and other countries in the European Union are doing the same. This is what worries me about the speed with which this Directive is being pushed along. There is so much more to be done. This is not defined well enough and we believe it will be quite meaningless to many and that a lot more work needs to be done on it.

Q340 Baroness Neuberger: I accept what you are saying, that you really do not like this, and I think Lord Inglewood has teased that out with you, but supposing we go ahead with this and you have to accept that there are some areas where we can already see this happening, so people presumably are making the system work. They are not particularly wealthy, the people who go across the border between Northern Ireland and the Republic. What would you say from the patients’ point of view the information ought to be like and who should provide it?
Ms Jennings: I think Lord Darzi does a very good job of describing what would be safe, evidence-based and probably that meets the needs of local communities. If that kind of criteria were applied to a contact point, then maybe that might be a way forward, but I would suggest to you that we are a long way off being able to provide that because we are having difficulty enough within individual nations.

Q341 Chairman: Can I pursue one question. If there were contact points, who do you think should provide them? Do you have a view?
Ms Jennings: No, I am sorry; I do not think we have thought that through enough.

Q342 Chairman: That is fine. Nobody has the answer. We are just pursuing and asking everyone. You do not have it.
Ms Jennings: If we may give some thought to that and write to you, then we will do that, but I am not promising.
Chairman: It is just interesting that no-one will tell us, and you will not tell us either, who the contact point should be. We are going to move on to this question of equity which you have referred to on a number of occasions. Lady Young, you are going to begin the equity questions.
Q343 Baroness Young of Hornsey: Yes. Obviously that is a concern for both of you, very strongly expressed in your written submissions. How do you think the inequity of the provision for payment upfront can be addressed? Do you think there should be a system in place to help those who do not have sufficient financial resources with the costs of travelling abroad to receive treatment?

Ms Jennings: We understand that John Bowis has suggested a voucher scheme, and, again, we would have some serious concerns about that. For example, we do have a tariff for secondary care in the UK and, therefore, we know exactly what a procedure would cost. However, there is no tariff at all for primary care. So for the very unauthorised treatment that you might go across to have care for, there is no costing for that, so I do not know how the UK Government are going to arrive at that tariff unless they start working on that straight away. So the voucher scheme would fall, in terms of those that are receiving unauthorised care, at the first hurdle, potentially. Also, the voucher scheme that has been suggested, again, would only cover the tariff, it would not cover any additional costs that might be met, and, therefore, we have serious concerns that it is unworkable on this basis.

Q344 Baroness Young of Hornsey: Do you have any ideas as to how it might be addressed in order to make it work in some way?

Ms Jennings: I know that the projects that the Department of Health had in the early days of inviting people to have their hips replaced in France or Germany provided for transport costs, but after the projects were over it did fall because there was no cost available for transportation. So, unless the NHS is going to pay out for that or the Government in some way is going to pay for that additional cost, then I really do not see how we can work it, but Karen may have some other views.

Ms Hutchinson Reay: Yes. It is the financial inequity that we have concerns about but I think it is also about widening it to look at inequity in other ways. The fact that there is a language barrier in health is a very big issue. I suppose, unfortunately, in the UK the vast majority of people can only speak one language—I think our colleagues in the EU are much more advanced in that—but it is a factor for our patients if they are going abroad. Also, maybe it is a choice. You are saying it is only those who want to go, but there is discrimination of those who would never be able to—those with childcare costs, those who would have to take extra time off work to go abroad. If they have not got an employer that is prepared to give them that time off, again, it would be a financial problem to those. As I say, you would have to pay more. What about carers for elderly people? Are they going to have to pay or are they going to be subsidised for the additional care that is required for the people they are caring for if they go abroad? So it is a much wider concept of inequity than just the financial one.

Ms Jennings: May I also say that I do not think anybody has looked at the costs of bureaucracy to support all of those transactional costs, and I really think a bit more evidence-based policy development around this would be helpful. Transactional costs are enormous and yet there is a serious failure to look at that, but if you look at what the transactional costs are in a market healthcare system in other countries such as North America, you will know they are spending double on their healthcare system than we are. So I think that might be something that could be explored further.

Q345 Chairman: But there are schemes already, are there not? There are schemes in this country—and getting from the North to the South of the country has its own issues—where people go for specialisms. Could that not be built on that scheme? Could we not learn from some of those existing schemes?

Ms Jennings: I am sure whatever we do should be evidence-based.

Q346 Baroness Morgan of Huyton: Carrying on this equity point but not looking from the UK position particularly on this one, I think Unison raised the issue about equity for people living in countries where the healthcare is low-cost at the moment, particularly somewhere like Bulgaria or Latvia. Can you expand a bit for us about what your concerns are around the equity issue for the people living in those countries and the effect on the healthcare systems there?

Ms Jennings: Yes, you are quite right to quote Bulgaria and Latvia, and I know also the Czech Republic is very worried about that. Also, there has been mention of Belgium and the Netherlands. Belgium has suffered enormously as a result of being a receiving country because it has meant that the existing citizens of that country have not been able to get the access to healthcare that they want. Also, I think we can take great pride in the fact that our waiting lists are at an historic low and certainly any opening up of opportunities to come in and be treated equal to UK citizens will certainly damage those waiting lists. So I think it is about citizens of those countries moving aside to enable in-coming people who are going to pay for their care, and it may well be seen in the internal market of healthcare within those countries that those receiving patients will be profitable, will generate income and, therefore, they may take priority over the citizens of their country. As I mentioned earlier, we know that in some of the countries, such as Poland and other
accession countries, that there are under-the-table-payments as well, which gives advantage to those who have the means to pay for that. So I think there are all sorts of problems for those countries. We know through dentistry that is happening already, and certainly, if you are increasing payments, then you are interfering with the universality of treatment in those countries.

Q347 Lord Lea of Crondall: Can I be the devil’s advocate on this for a moment? You have mentioned waiting lists, and some of us have been asking other witnesses questions about waiting lists. How come suddenly there is nothing to do with waiting lists and queueing or queue jumping and anything like that, and the answer is in this system that should not happen, but if you say that we have got a full house and then people come in, does that not pre-suppose that you know that more people come this way than go the other way? That is the first point. Let us say it is 100,000 people come this way. Do we know that there are 100,000 people going the other way, or more or less? Maybe one has to begin with the best presumption and it may be 50:50, or something like that. Transaction costs: obviously we all know that is a presumption and it may be 50:50, or something like that. Transaction costs: obviously we all know that is an issue, but can you comment about the fact that our perspective may be a bit asymmetrical?

Ms Jennings: The first thing that comes to mind is that, for example, if we use cataracts, if getting day treatment for cataracts is something that is highly specialised in Poland or in the Netherlands and it would be cheaper than here, we could find an influx of patients going across there, and what may happen may be similar to what happened around the independent sector treatment centres, which is that you start to lose that specialism from the NHS and, therefore, if you are then trying to get treatment on the NHS in your country of origin, close to home or just in your country, it becomes more and more difficult because those specialisms move away and that will then have an impact on our waiting lists.

Q348 Chairman: On equity, are we being a little parochial if we say our waiting lists are down and, therefore, if there are a number of people in another country needing a particular treatment and we see ourselves as Europeans we are going to do our best to keep them out? I am being provocative in my question, but that is what it sounds like.

Ms Jennings: Yes, I am sorry it sounds like that, it is not intended to sound like that, but I think if you take the context of my previous answer, which was that we could be stripping a specialism from another country to this country and vice versa, then that is the context in which I was answering that and not that we would not welcome people coming into the UK to benefit from expertise. In fact, we are already doing that. There is already provision for that, and that is why this is such a dog’s dinner, because it does not take into consideration the articles and regulations that already exist for cross-border healthcare.

Chairman: Which leads us nicely into Lord Eames’ question about co-operation.

Q349 Lord Eames: Good morning. We have probably touched on this already this morning, and I think none of us has any doubt as to your general opinion on the Directive, but could you say something to us about the provisions, as they stand at the moment, of co-operation between the Member States? I am thinking particularly of practicalities like cross-border prescriptions and things like that. Is there anything you would like to add to what you have said already?

Ms Jennings: If I may take that exact example, I think one of the things that this Labour Government has done is to set up the National Institute of Clinical Excellence and should be congratulated for that, and it is being strengthened and it is being improved upon, but what it does do is recommend what is the most efficacious drugs that Health Service practitioners can prescribe. They do not have that in the rest of the European Union, and what you can find is that if somebody accesses healthcare in another country, a doctor may be prescribing a drug which is not recommended by NICE; NICE might be recommending something else. So I think, in terms of even prescriptions, there is a real difficulty. I know other European countries are starting to look at NICE and may adopt a similar model, but it is examples like that that demonstrates there are real inherent differences, and also that each nation is very wedded to the healthcare system that they have and very proud of their healthcare systems in the same way that we are of our system, and this Directive, I think, seeks to undo those national differences.

Q350 Lord Eames: But if, per chance, the Directive finds the light of day in substance, what are we going to do about the question of prescriptions? If we are objecting to the Directive in total, we need to face up to the fact that this difficulty is going to remain. So have you any ideas to share with us about how that could be dealt with?

Ms Hutchinson Reay: I think the point that Karen makes about NICE, and it is about clinical excellence, best practice and clinical governance, and our objective, surely, is to have a high standard across the EU for all, and other countries are looking at NICE and looking at the regulation of drugs. There is one other issue that sets us aside to some extent, that nurses can prescribe in the UK now and are advanced prescribers as well, so their listings are much wider, and that has to be taken into account. Often drugs, as Karen says, are prescribed for long-term periods. I do not know how that would affect
the UK. You know, somebody goes abroad, has whatever treatment, and is prescribed a certain drug. Even the costings of such drugs will come back and hit on the primary care trust, or the acute trust, the foundation trust in the UK. So to answer your question, I think eventually it would be a real utopia to have that concept across the EU, but with the culture that we have and the systems that we have, not being too negative, I cannot see how that can happen in my lifetime.

Ms Jennings: May I come in and follow through. My colleague behind me has reminded me that the Department of Health is already addressing this issue around co-operation on prescriptions and e-health with other Member States, so I am not quite sure why we need extra elements of this in terms of this Directive if that is already going on. If we have talked earlier about evidence-based, should we not be looking at what they are doing already and developing policy around evidence rather than creating something here through this Directive?

Chairman: I am going to move on to liability and redress, and Lord Kirkwood is going to pursue this issue.

Q351 Lord Kirkwood of Kirkhope: Can you clarify in my mind exactly what your position really is? If it is a question of a choice between a dog’s dinner and a status quo and you are forced to choose, would you both say that you would prefer to stay with what we have for the moment? If so, is it sustainable in the long run?

Ms Jennings: There have been four legal challenges. There are already regulations which enable cross-border healthcare, so we would actually favour this not going through and taking time to look at a proper debate around this and redrafting this at a later stage. I think for this to go through there will actually be legal challenges on this Directive, because there are elements of it which are not thought through and ambiguous and, as I said earlier, if there are not legal challenges in Europe, we will certainly have them here.

Q352 Lord Kirkwood of Kirkhope: But the implication of that is that something has to be done?

Ms Hutchinson Reay: Yes.

Q353 Lord Kirkwood of Kirkhope: Is that right?

Ms Jennings: I would say, yes.

Q354 Lord Kirkwood of Kirkhope: Do both of you feel that something has to be done?

Ms Hutchinson Reay: Not based on just four cases. It is more about looking at the qualitative aspect of healthcare in the EU.

Q355 Baroness Morgan of Huyton: Can I add a supplementary to that? Am I right that what you are saying is that from your point of view in the UK, for UK patients, you think there is a detrimental factor? There is probably, largely, a detrimental effect on the UK National Health Service as it is at the moment if this goes through as it is, but that, arguably, in some other countries, because they already are experiencing a lot of cross-border movement, there may be more need for it or more demand for a Directive because they are already experiencing a large amount of movement? From your colleagues, because, clearly, you talk a lot to people in other EU countries, is that your impression?

Ms Hutchinson Reay: No, I actually think from the unions or across the EU our position is the same, is it not, that there are problems from all countries. They may be different problems and they may be different concerns but, as Karen says, it is the fundamental flaw that how the premise of the Directive has been set in the first place rather than looking at quality assurance in healthcare and raising standards across the EU. This is much more a knee-jerk reaction to four court cases that came through.

Q356 Lord Kirkwood of Kirkhope: I am looking at Unison’s evidence at paragraph 14. You say that the Directive’s approach, in your view, with regard to redress and professional liability is too simplistic, and you go on to characterise that, saying, for example, that the environmental context, the buildings and the environment in which the worker is providing health services could have an important bearing. Is that the ceiling falling in? What does that mean? Everyone understands if a surgeon makes the wrong cut with the surgeon’s knife. What else are you talking about?

Ms Jennings: I am happy to answer that question, Lord Kirkwood. In the NHS we have a system of vicarious liability. That means there is a mutual duty of trust and confidence between the employee and the employer, and the employer has to provide a safe environment for the workers but also for the patients. One of the advantages of the system that we have in the NHS is that we are not litigious, we are not a litigious society, and if there is negligence on a patient or if something goes wrong, it is the hospital which compensates, not individuals. This Directive is placing the responsibility upon individual practitioners. To give you an example, it is referring individual practitioners to have indemnity insurance to be able to be registered to practise.

Q357 Lord Kirkwood of Kirkhope: Do you know that other European sister nations do not have this vicarious liability that we do that would provide cover for that situation? Do you know?

Ms Jennings: Under health and safety legislation, employers have to provide vicarious liability.
Q358 Lord Kirkwood of Kirkhope: Surely that is true in sister European nations as well?

Ms Jennings: Yes.

Q359 Lord Kirkwood of Kirkhope: So what is the problem?

Ms Jennings: The problem is that, if you require individual practitioners to have indemnity insurance, they will be sued, and at the moment they cannot be sued in the United Kingdom. The only area where practitioners are required to have their own indemnity insurance is if they are individual practitioners who are self-employed. Independent midwives are a very good example of that. If you think of a midwife, she has to pay the same indemnity insurance as a consultant, earning maybe a third of their salary, and that is because the risks are so high. If we require our individual practitioners to have indemnity insurance, you are inviting them to be sued.

Q360 Lord Kirkwood of Kirkhope: Lord Chairman, can I have a note on that? Would you mind? I am struggling to understand it, and it is a very important point.

Ms Jennings: It is a very important point.

Q361 Chairman: We had quite a lot of evidence on indemnity and we gained the impression that certainly most doctors, we understand, are insured either by indemnity or by the insurers.

Ms Jennings: That is correct.

Q362 Chairman: That is different, I assume, from a number of other practitioners within the Health Service?

Ms Jennings: Absolutely; that is right. Nurses are not required to have indemnity insurance. We are concerned that if you start making the individual practitioner responsible that you then remove the responsibility from the employer to provide a safe environment. If you think about an employer, when they consider a safe environment it is not about the roof, it is also about the education and training that the staff have and the cleanliness of the hospital.

Q363 Lord Kirkwood of Kirkhope: If you moved the responsibility to the employer, you would be happy.

Ms Jennings: The employers already have that responsibility, so why do you need to, in this Directive, say that individuals have to be indemnified?

Lord Kirkwood of Kirkhope: I see.

Q364 Chairman: Do you think the question is about precision over which practitioners? I suspect that the Directive, because it is based on the four cases, is linked to doctors and that kind of care and has then encompassed general medical care where some of the difficulties lie, and that is what we are trying to tease out, because only if we tease those things out from you can we supply that evidence. Does that sound logical?

Ms Hutchison Reay: Yes, it does, because the vast majority of people, when they look at any healthcare, will look at a medical model, and the fact is that the vast majority of healthcare that is delivered is by non-medics. So, yes, you are absolutely right.

Q365 Lord Kirkwood of Kirkhope: Would you mind doing a little note to flesh that out?

Ms Jennings: We would be very happy to do that.

Q366 Lord Kirkwood of Kirkhope: That would be a real help. Briefly, UNISON also refers in its evidence to inadequate consideration of compensation procedures which you think might be complicated and expensive, but compensation procedures are not always complicated and expensive. What more consideration is going to make that easier? Are you not stuck, in any system, whether it is cross-border or not, with compensation claims? We do not live in a litigious society in the United Kingdom compared to other nations, arguably, but how does further consideration help us to solve the problem of litigation and complication?

Ms Hutchison Reay: I think, as you rightly say, any litigation of compensation is complicated but it is exacerbated by other issues like language, different legislation in different countries, that would make it even more of, as Karen says, a dog’s dinner.

Q367 Lord Inglewood: Can I ask you for a moment to look forward and assume that your worst fears are realised and that the Directive takes effect. I think we can agree that we are going to be living in a world where there are going to be two kinds of cross-border health cases, what I can call for shorthand E112 cases and Directive cases. Do you think it will be easy to make the distinction between which and which in the real world? There are bound to be disputes, and I am sure we can agree, if on nothing else, that it is a pity if that ends up in court all the time. So how would you deal with that sort of dispute and what sort of appeal system might you envisage?

Ms Jennings: I am not sure about the premise of the argument that there is going to be a lot more cross-border healthcare and so we might as well try and develop something. I do not even think there is going to be a lot of holidays in the next few years given the credit crunch situation and unemployment right across Europe, so I am not so sure that we are trundling on a fast train towards a lot of cross-border healthcare. As I have said, I think that there is so much work to be done on this that there is no need for
this level of haste. We are not saying that something should not happen, but we need to look at the evidence and we need to plan a lot more carefully, because what is here is not good enough and not amendable.

Q368 Lord Inglewood: I entirely understand the point you are making, but I suppose the conclusion that, if you were me, you might draw from your remarks is that actually this is not going to make much difference in the real world, and I would then retort to you and say, that being the case, what is the problem if it is not going to cause a problem?

Ms Jennings: I am sorry?

Q369 Lord Inglewood: I thought that you had said in response to my question, which was not a reply to it but, nevertheless, was a perfectly legitimate response to it, that actually we think there is going to be so little cross-border health activity that this issue that I raised about the distinction between the two classes of case was not going to be a real problem. Then my point to you was, that being the case, it would suggest that you think that actually this Directive, if it were to come into effect, is going to be pretty much a dead letter. I then say to you, if it is going to be such a dead letter, why are you so vigorous in opposing it?

Ms Jennings: We are so vigorous in opposing it because it creates a two-tier system, and once you introduce a greater market—well, it creates perverse incentives, quite honestly. I think you will start to get countries that want to make money advertising and, as you have said yourself with dentistry, there is a lot more people accessing dentistry in countries where it is cheaper, and it may well affect other European countries more than it affects the UK because we are an island and so it may well be more difficult and more expensive for people to come to here and to travel over. I do care about the European Union and other countries; I do not like the idea that in poorer countries and in accession countries, wealthier countries will take advantage of the system and I would not want to be something that supports two-tierism whether it is here or within the European Union. So that is why.

Q370 Chairman: Would you, therefore, not say, if this was implemented, should there not be a method of, not only prior authorisation, but acceptance or non-acceptance by the health authorities? It is set in the context of your thought about waiting lists, provision and equity. Who actually makes the decision about priorities and how would that work?

Ms Jennings: If you are forced into a corner to discuss this, which I guess we are, then I would suggest that you would leave prior authorisation up to individual countries, and that it is something that should not be just left to the definition of an overnight stay, it should also include primary care. That is my answer to that really.

Chairman: I think that is a helpful comment.

Q371 Baroness Gale: My question is dealing with the pathway of care. Do you consider that the draft Directive does not deal adequately with the question of aftercare and the application of a more holistic healthcare model? How do you think the Directive might be amended to overcome this weakness and to what extent are you content that there are sufficient safeguards in the draft Directive to facilitate a safe pathway of care so that the aftercare which you refer to could be delivered in the home Member State?

Ms Hutchinson Reay: Thank you. The whole concept of holistic care seems to be missed out of this Directive, which is one of the major concerns that we have; that an individual is seen as a very complicated person and that the needs of that individual are pre and post whatever care is required—so it is a pathway from the beginning of diagnosis right through to the care that they actually have and the aftercare—and when we say “holistic care”. It is not just the physical, it is the emotional, psychological well-being of an individual, and this Directive does not address any of that whatsoever. We are very, very fortunate in the UK that we have community services that are historically well advanced, and the whole movement of Lord Darzi, which we have mentioned before, is about that caring community. The vast majority of people want that care delivered close to their own home where their families are, where they can gain support. If you were diagnosed with a devastating illness, you need your family around you. It may be that that illness is treatable, but maybe it is not; you have to go abroad. What about those families? What about the psychological effect on those families? Can the Directive actually be changed to address those things? I think, as Karen says, we need to seriously look at the evidence-base that we have quite a lot in this country already about holistic care and communication pathways in the managing of care. I do not see that anywhere in this Directive, which is a fundamental loss.

Ms Jennings: May I also reinforce the point that aftercare is something that is often prescribed by the clinicians that have provided whatever procedure they have and, therefore, there is a whole issue around language, the directions for the aftercare and also patients’ records. You know, what happens to those and what is the compatibility between the countries and what do you have in place where you are returning to? If it is a particularly specialist procedure that you have, who near your home has been trained in that aftercare?
Q372 Baroness Gale: I can see what you are saying and the difficulty of it all, but how do you think that can be overcome? If a patient from the UK goes abroad to one of the European countries, they obviously will need aftercare. Are you saying that the whole package should be arranged before the event, so that the patient is quite clear what is going to happen and that the aftercare will be provided back home, in their own country? That person is totally aware of the whole procedure, how the package is going to be delivered, but are you saying that you do not see that in the Directive at all?

Ms Hutchinson Reay: If you are looking at packages of care, I think you are right, you have to decide—especially if it is surgery and it is opted surgery rather than emergency. That package of care is developed beforehand, and if it is going to be delivered in the country where you have the surgery or when you come back to your home country? That will have to be all costed out. I think you also have to make an agreement of a first language that is going to be there because you are going to have different professionals giving different services—physiotherapists, occupational therapists, to name just a few. If you are looking at holistic packages of care, they have to be defined before an individual person makes that informed decision of what they are going to do.

Ms Jennings: This is not impossible. There are technical difficulties there. You would almost have to have worked out that package beforehand. That means that the PCT who commissions services, procures services, will need to have had detailed discussions, will have had to have preparation and training for the staff. It is highly complex. It may well be that a PCT will have commissioned a specialised service that they have recognised is needed in their local community, but if it is a one-off or an unusual treatment it is highly unlikely that all of that would have been put in place, I would suggest, near to home.

Q373 Lord Cotter: You have spoken about liaison and you have referred to EPSU. Is there a formal system of liaison? Karen of UNISON, you said you cared about other countries and what they had. Do you have a formal system? Does it operate in all countries? Is it comprehensive, so that you can really get the information about what others feel? You have said you are concerned. You are all concerned. Is there such a system in operation on a regular, sustained basis?

Ms Jennings: I am President of EPSU’s Health and Social Services Committee. It has membership of every country and accession country in the European Union and beyond that. We have had high level discussions with all affiliates—and, by the way, Unite is a member also, as are the Royal College of Nursing, the Royal College of Midwives, the Chartered Society of Physiotherapists, and the President of the Association of Nurses for the European Union sits on that Committee. That Committee is the formal partner in social dialogue with HOSPEEM, which is a managers’ organisation. We are at the moment discussing about four areas of work in relation to developing European legislation, including needlestick injury, cross-border healthcare, and so on, so we are responding formally to the legislative processes within the European Union. It is the most representative body of healthcare workers—including, not from the UK, but doctors across the European Union.

Q374 Lord Lea of Crondall: I am a bit baffled. Perhaps I could put this question to Karen Jennings, who holds a very senior position in the social dialogue. How on earth has it got to this position for all the trade unions, including all employee organisations under that broad title, and the employers?—and I do not know where the European Parliament yet is. The Commission caricature is that they dream up a proposal and all the rest of it but they claim that they have had all sorts of researches that lead to the proposal. What happens when you meet the Commission and go through all this lot? At which stage do you just say, “Goodbye, we do not agree with you” and walk out the door? How does it work?

Ms Jennings: This definitely has an impetus to it. This is about the internal market rather than health care, we believe.

Q375 Lord Lea of Crondall: What do they say?

Ms Jennings: They deny that. This requires co-decision of the Parliament as well. We are working with MEPs and with the affiliates of EPSU through their members of Parliament. Indeed, I have met with Dawn Primarolo and special advisers and civil servants. We are doing what we can from within this country. Certainly all the Health Service trade unions under the TUC are doing what they can and are very supportive of what Karen and I are expressing today. There is a groundswell of opposition to this and concern.

Q376 Chairman: Are you saying to Lord Lea the Commission are not listening to you?

Ms Jennings: The Commission are saying that they are consulting. In that respect, they listen, but they are very aware that there is a great deal of opposition to this.

Q377 Lord Lea of Crondall: It has got this far without any meeting of minds. This is a fairly late stage, in fact. It is not just a Green Paper, is it?
Ms Jennings: You may recall that this was distributed just before the summer recess, which was very poor timing, I think, and within 24 hours was pulled back again and there was a seismic opposition at that point. I have to say that our own Department of Health were saying, “Absolutely no way.” In between that time and now, there appears to be, “Let’s see what we can do and work with this.” I am afraid I think it is just such a mess.

Supplementary memorandum submitted by UNISON

Article 5(1) of the proposed Directive refers to the need for systems of professional liability insurance. UNISON is keen to ensure that the Directive does not result in a system in which individuals across the healthcare team can be sued directly when something goes wrong, which seems to be the implication.

As it stands in the UK, nurses and many other health professionals are not required to have indemnity insurance (unlike doctors). Rather, vicarious liability resides with the employer where a patient seeks legal redress.

Under health and safety legislation, employers are required to provide a safe environment for patients and staff. Potentially the Directive could lead to this responsibility being taken away from the employer and placed on individual employees instead.

Individuals indemnifying themselves will only really benefit the insurance industry and would take place at great cost.

As pointed out by the Chair of the Committee, this may be because the Directive overall is predicated on a medicalised approach to healthcare rather than recognising the different strands of the healthcare team that are so important to care in the UK (and other Member States).

UNISON understands that this issue of professional liability is one of the areas where EPSU (the European federation of Public Service Unions) has yet to hear back from the European Commission despite raising concerns.

December 2008

Supplementary memorandum by Unite

Unite shares the concern expressed by UNISON in their written and oral evidence to the House of Lords European Union Sub-Committee G that the European Commission’s view of professional liability is too simplistic.

Currently, those working in the NHS do not generally need to have professional indemnity insurance. Instead they are covered by their employers’ vicarious liability insurance. This recognises the importance of the employers’ responsibility to deliver safe health care, in a safe environment and ensure staff are well supported and trained.

Unite is concerned that the European Commissions’ proposals places the emphasis on individuals being required to have indemnity insurance. This removes the recognition of employers’ responsibilities as mentioned above. Unite is concerned that in future if individuals working for the NHS are required to have individual professional liability insurance the European Commission is opening up those individuals to litigation, and will increase the incidence of litigation.

January 2009
**THURSDAY 15 JANUARY 2009**

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**Examination of Witnesses**

Witnesses: Commissioner Androulla Vassiliou, EU Health Commissioner, Mr Philip Tod, Member of Cabinet of Commissioner Vassiliou, and Mr Bernard Merkel, Head of Unit, Health Strategy and Health Systems, Health & Consumer DG, European Commission, examined.

Q378 **Chairman:** Can I just welcome you to the Committee and say how grateful we are to you for giving your valuable time to come to talk to us. Our inquiry we see as fairly important in this area and we are near the end, we are coming to the conclusion, so we thought it was extremely important that we were able to talk to you at this stage and really try and clarify some of the points which have come up when we have been talking to other witnesses, so thank you very much indeed. If you wish to make supplementary evidence and make any points where you think we may not have got clarification on during the time, then it would be very welcome. Also, although I know we all know who we all are, I have to ask you, when you begin, to state your name for the record and I would ask you if you would like to make an opening statement.

*Commissioner Vassiliou:* Good morning. My name is Androulla Vassiliou and I am the European Commissioner for Health. I must say, it is an honour, and a privilege, for me to be here with you and introduce, although I am sure you know a lot about it, and discuss with you, the provisions of the Directive on Cross-Border Healthcare which we believe is the most important Directive on health of this Commission. So, if you will allow me, My Lord Chairman to make an introduction to the provisions of the Directive and then of course I am open to questions and dialogue with you. As you know, in recent years, we have seen a number of judgments of the European Court of Justice on the subject of cross-border healthcare. One of the latest cases concerned a UK citizen, Mrs Watts, who underwent a hip operation in France for which the NHS refused to pay. The situation has become really complex as these rulings of the Court were each dealing with different individual cases and the main principles now need to be interpreted and translated into a general framework. This cannot be done by the 27 Member States separately and we feel that we have to do it for them, or with them. My aim with this initiative is to provide patients with better opportunities and access to healthcare, regardless of their place of residence, while fully respecting the national responsibilities of healthcare systems. This is why the proposed Directive focuses on patients. It aims to help them exercise their rights by providing them with more transparency and assurances about the healthcare they will receive. The Court recognised the right of patients to be treated in another EU country, but how can we give patients the right to choose where to be treated without providing them with the necessary tools to be able to make an informed choice? The lack of information would make this right impossible to exercise or would lead some patients to make the wrong choice; that is what we want to avoid. The proposal also aims to clarify the conditions under which patients will be entitled to seek cross-border healthcare and be reimbursed. By this proposed legislation, patients would be able to seek any healthcare abroad that they would have been provided at home. They could be reimbursed up to the amount that would have been paid had they obtained the same treatment at home, but they may have to bear of course the financial risk of any additional costs. The Directive also pursues another important objective which is too often overshadowed by the European Court of Justice case-law aspect. The proposal aims to establish a new framework for closer and improved co-operation in certain healthcare-related matters. This, I believe, is where the major challenges and opportunities lie ahead. My aim, as European Health Commissioner, is to help ensure the highest level of public health in our Member States. To do this, we must use all the means, tools and competencies available at European level to support Member States’ actions and policies. In doing so, we can respond to the needs and concerns of our citizens. The proposed legal framework is structured around three main areas. First, it clearly reaffirms the common principles of EU health systems: universality; equity; access to good-quality healthcare; and solidarity. It recalls the overarching principle underlined by the Treaty and
the Court that the Member State on whose territory the healthcare is provided is fully responsible for setting the rules and ensuring compliance with these common principles. To help the Member States apply this principle, we have proposed to clarify the responsibilities of the Member States in terms of the quality of health and safety standards for healthcare provided on their territory to patients from other Member States. The proposal will also help improve the current situation in terms of transparency and information on cross-border healthcare provided to patients. Appropriate information for patients is a necessary pre-condition for improving patients’ confidence in cross-border healthcare. The proposed Directive, therefore, requires that information to patients regarding essential aspects of cross-border healthcare is easily accessible to them and that national contact points for cross-border healthcare are established. Second, the Directive makes clear the entitlement of patients to receive healthcare in another Member State and the conditions which apply. At present, the Court’s jurisprudence is, in some cases, poorly understood and it is often disregarded or unevenly complied with. We have also clarified that, under some circumstances, Member States are entitled to introduce a safeguard to restrict the reimbursement of healthcare obtained abroad, for example, through prior authorisation for hospital care if there is a clear risk, or even the possibility of a risk, of undermining the national health systems, but, as the European Court has ruled, prior authorisation should be seen as an exception. It should be applied in a proportionate and limited way and only in specific circumstances. I know that some Member States may have difficulties with this provision, but I believe that the approach taken by the Commission is the only possible way forward. In addition to this, the Directive clarifies the definitions of hospital and non-hospital care, thus simplifying the procedures and conditions necessary to access cross-border healthcare. In this context, I would like to stress that we have maintained the possibility to expand the concept of hospital care to cases of healthcare which do not necessarily require an overnight stay, but which are, by nature, costly or need a heavy infrastructure to be properly delivered, for example, PET scans, gamma knife or radiotherapy treatment. The proposal also clearly recognises that Member States may maintain general conditions and formalities, such as the requirement to consult a general practitioner before consulting a specialist and, also in relation to patients, seeking healthcare in another Member State, but of course these conditions should not be discretionary, discriminatory or disguised barriers to free movement. Third, the Directive establishes, as I said before, a new framework for European co-operation in areas that we have identified as key areas for the future and where we must act together at EU level to better meet the challenges ahead of us. This is done in line with the principles I mentioned earlier through streamlined and improved co-operation, common technical guidance and systematic research for best practice. This framework will allow for enhanced future collaboration at the European level in areas such as European reference networks with a view to pooling expertise, knowledge and medical skills for diagnosis and treatment for the benefit of all patients; health technology assessment, whereby the most efficient therapies will be identified at EU level by experts from the Member States, and this information is spread in order to promote their views; e-health to maximise the use of information and communication technologies in health; a more co-ordinated approach at EU level on the collection of data related to cross-border healthcare in order to better monitor the effects of the proposed measures and enhance our epidemiological surveillance; and, finally, of course the better recognition of medical prescriptions issued in another Member State. I hope that these new measures will help to realise the huge potential of pan-European co-operation in health. Our aim is not to increase bureaucracy or to impose one single approach, but to focus on areas where key challenges can be better addressed through coherent and co-operative approaches. To conclude, our goal is to help citizens receive appropriate healthcare wherever they are in Europe. This does not mean promoting mobility just for the sake of it, but it does mean ensuring clear rights and rules for providing the most appropriate solution for a patient for a particular case. Let me be clear, we are not changing the rules of the management of healthcare systems. Member States are responsible, and remain responsible, for deciding what benefits they provide to their citizens and what treatments and medicines they will pay for. This will remain the case. This proposal, we believe, is in line with the Treaty on the one hand and fully respects the competencies of the Member States on the other. Thank you for your attention and I am now at your disposal.

Q379 Chairman: Commissioner, thank you. That was, I think, helpful and enlightening for us. Your presentation has very clearly outlined the principles with which, I think, most of our witnesses would have agreed. I think the difficulties are in application and in practical management of the Directive, and I am sure that many of the questions that the Committee will want to ask will be about how we keep these proportionately together. Everyone we have heard from has agreed that there needs to be a framework following the legal findings, but there has been a great deal of difference about how that framework should
be put into practice, indeed how that framework should look, and also the extent to which the proposal fully respects the provisions of the Treaty and, most notably, Article 152, that, “Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care”. I think it is important just to say that as it is in 152 because there has been a great deal of difference between our witnesses about how that is viewed. We would be grateful if you could briefly outline the Commission’s rationale for choosing the internal market, Article 95, as the legal base for the Directive, if we could start there, and to what extent are you and the Member States content that the proposal respects the boundaries of Community action as laid down in 152 of the Treaty?

Commissioner Vassiliou: The choice of the legal base is not a political choice of the Commission. It follows from the various decisions of the Court who based their judgments on the provision of the freedom of movement of persons, goods and services in the internal market, and that is why we could not deviate from that decision, but, at the same time, we keep 152 in the centre of our Directive because we stress under the Directive that the Member States remain responsible for the organisation of their health systems and, as I said, what benefits they decide to offer to their citizens and what medicines they would like to offer, and then we have a diversity of national health systems and of course we shall maintain this diversity. The point is that we have been asked both by the Parliament and by the Council to have an initiative on this subject where we take into account the specificities of health and healthcare, and we believe that, with this legal base, we can do that and that is why we have, for example, put in provisions regarding quality and safety and about information. All of this could not be done if we had chosen another legal base.

Chairman: I think that the legal base is one thing. The way that that will affect citizens and the services is something that we have been very concerned about, and Lady Morgan is going to move on to the first question that actually is practically about that.

Q380 Baroness Morgan of Huyton: Can I look at the right of refusal of Member States in terms of incoming patients because obviously you have emphasised to us this morning that Member States will remain absolutely responsible for the organisation of health services in each State, but how, in practice, would the right to refuse incoming patients happen were that deemed necessary in a Member State? The draft Directive states that this can be done if there is going to be a detriment to patients in a Member State if incoming patients are given treatment ahead of those needs, but do you think that is clear enough in the Directive at the moment or is there any way you think that that could be explained more clearly to those reading the draft, and is there going to be any sort of appeal process in terms of the right of refusal?

Commissioner Vassiliou: First of all, we must all recognise that the primary responsibility of Member States and their service providers is to provide high-quality healthcare to their own citizens, so from this we infer that of course they have the right to refuse treatment to other EU citizens if they have no capacity and if this would create a detriment to the healthcare they can provide to their own citizens, provided, as we say in the Directive, that this decision not to accept is not discriminatory. That is why, I think, we have to give emphasis to information because, if, let us say, the UK healthcare providers think that they have no capacity to offer hip replacements, they would immediately give the information to their other fellow members in the EU that, “We cannot take any more citizens for hip replacements”, so, when the citizen goes to their contact point for information, they will tell them, “Don’t bother because there is no capacity”, but our objective is that, if there is surplus capacity in one Member State and surplus demand in another, why not balance the two, which would be to the benefit of all of them, but this will not deny the Member State the right to refuse planned healthcare in a Member State.

Baroness Morgan of Huyton: Thank you, that is very clear.

Chairman: One of the areas we have found really difficult is getting people to talk about contact points and information, and Lady Young is going to pursue that.

Q381 Baroness Young of Hornsey: You have already mentioned this issue of information and the potential role of contact points, so I want just to get a little more from you on that. Can you explain in a little bit more detail what you consider the role of the national contact points to be and how they should be funded, as this is something which has come up in our inquiry. Also, what EU-level role might there be in assisting with the establishment and day-to-day running of national contact points and the information they provide? Finally, who should be responsible for the direct provision of information to patients?

Commissioner Vassiliou: First of all, as I said before, we consider that one of the added benefits of this Directive is to protect the citizen who wants to go abroad to receive healthcare from going and finding something completely different from what he is expecting. We want to protect our citizens, therefore, we want to give them as much information as
possible which will render them able to make an informed choice, so what exactly the Member States will exchange between themselves with regard to information, this will be decided at a later stage among the representatives of Member States. For example, I am sure that they will decide that at least it makes sense that they will give information about the capacity of their hospitals, about the costs of their treatments, about the reimbursement and the mode of reimbursement both of the treatment, but also compensation in case of harm, so all this, I think, is information which will be exchanged. Coming to the organisation of these contact points, each Member State will decide how they will organise it. Some Member States have already centres for information for other things, so they may include this specific information within the ambit of some other centres that may exist. Some Member States may decide that they will have only one contact point in the capital of the State, or they may decide that they want to have them also in the regions, depending on the particular circumstances. Now, when the contact points are set up, there will be a network of contact points, and that is where the Commission comes in to help with the management of the network of contact points and see how best we can organise the management of these contact points. For the time being, I do not think we have any provisions regarding money to be given to Member States for the organisation, but, as far as the management of the network is concerned, yes, we shall have an active role in helping Member States.

Q382 Baroness Young of Hornsey: Is there a structure, or do you envisage that there will need to be a structure, in order to deal with that discussion because it seems to me that there will need to be, again as other witnesses have confirmed, consistency about the content, so how will that discussion be facilitated to take place in order to ensure that the national contact points have some degree of consistency across the EU? Commissioner Vassiliou: Under Chapter 5 of the Directive, we provide the comitology procedure for a number of things and one of these is the way the information will be organised and then the management of the network of contact points, and of course, through the comitology in which all the representatives of the Member States, the experts of Member States, will be participating, they will decide what information they have to provide to each other and they will be consistent of course. You cannot leave it to each Member State to say, “I want to provide you with these three bits of information” when the other will say five, but it has to be consistent and this will be agreed after the approval of the Directive and we have set up a procedure of comitology. I do not know if Mr Merkel wants to add anything to that.

Mr Merkel: Yes, and I am Bernard Merkel, the official in charge of the unit on health strategy and health systems, only just to say that it is absolutely crucial that the information is agreed between the different Member States and also that it is a sort of validated process. There is no point in information just being given out which actually each Member State does not think is sensible and correct, so each Member State has to be in charge of its own system, but, as the Commissioner was saying, there needs to be very good networking between the Member States in terms of what the information is going to be, how it is provided and so on and we can help to facilitate that, and it is possible that there might be some money, although I would not make any kind of commitment!

Chairman: We think that this is going to be a major issue and I hope, when you receive our Report and hear the issues raised by other witnesses, that you will understand how complex the people on the ground see this and indeed the size of it, and Lord Lea is going to pursue this issue of prior authorisation which is a thorny issue, but also a little about the proportionality of the issues.

Q383 Lord Lea of Crondall: It does also relate to the comitology in Chapter 5 of the Directive which is explained in the Explanatory Memorandum in Chapter 4. There are obviously potential benefits and drawbacks of any system, but, on prior authorisation being granted, you have got the health authority of the Member State of affiliation of the citizen establishing agreement with the patient, or Member State of treatment, in order to clarify where the responsibilities lie along the pathway, but perhaps you would comment on the balance of those benefits and drawbacks of that particular way of doing the system. Some of our witnesses have told us that the existence of this Directive and of the E112 system could cause confusion as to which ought to be relied upon in different circumstances and, furthermore, as to whether or not prior authorisation is actually required, so how do you think that this confusion could be overcome and possibly whether some amendment to the proposal might be needed to provide the clarity which we are doubtful exists at the moment.

Commissioner Vassiliou: The intention is, and it is, in my mind, clear in the Directive, but I want to stress it, that, whenever the requirements of Regulation 1408 apply, and I will explain them, these should be given priority. Why is this? Because, for those cases which fall under Regulation 1408, patients are reimbursed according to the more beneficial tariffs, which would often mean fully for the whole cost of their healthcare.
abroad, sometimes also including the cost of travel, accommodation and sometimes even the expenses of a person accompanying a small child or an elderly person and so on. Which are these cases? First, it is people travelling as tourists abroad, students and workers who happen to be in a foreign country and, if they fall ill, they will go to a hospital in the other country and receive treatment and be reimbursed directly by their home Member State. It is also citizens of country A who need urgent treatment and the country of affiliation is not in a position to offer this treatment immediately and within a reasonable time as it is needed. Of course, again with prior authorisation, he will be sent abroad to receive his treatment and again be fully reimbursed. However, the Court said that, on top of these special cases, the citizen has an inherent right to receive healthcare abroad whenever he or she may so decide, but of course, in order to protect the health system of the citizen, “I am prepared, in your case, to pay the full amount”, but it is up to the Member State, so we do not want to put the Member State in danger of it happening. Now, of course this does not mean that the home country cannot say to the citizen, “Yes, he or she will be reimbursed for this treatment abroad, but up to the amount that it would have cost if he or she had received the treatment at home”, and that is why they put in this ceiling of “up to the cost of the treatment at home”. Now, of course this does not mean that the home country cannot say to the citizen, “I am prepared, in your case, to pay the full amount”, but it is up to the Member State, so we do not want to put the Member State in danger of it affecting their health systems and that is why we have put in the ceiling. Now, prior authorisation was expressly referred to by the Court in many cases and they said, “Yes, we have to recognise the right of a citizen to make this choice. We cannot present impediments to this right, but, if we need to put in some conditions, these exceptions”, and they called it “exemptions”, I think, “should be really the exception and should be reasonable and proportionate”. If a Member State, from the very beginning, says to its citizens, “There is no way that we will accept to reimburse you for treatment abroad without prior authorisation” without any evidence that the application of this Directive may damage its health system, we believe it will be considered by the European Court as disproportionate and will be ruled out. It is not up to the Commission to decide that, but we believe that we shall end up in Court to decide whether this general prior authorisation is reasonable and proportionate, and that is why we put these conditions to it. The Court said clearly, for non-hospital care, no prior authorisation, and it was very clear about that, so, if a Member State puts in place prior authorisation for non-hospital care, it will certainly be ruled out by the Court, and, for hospital care, it is only such prior authorisation that we believe is necessary if we are running a risk of damaging our national health systems.

Q384 Lord Lea of Crondall: I just have one supplementary, if I may, and that is to do with proportionality. There are two meanings of proportionality and, I suppose, one of them is whether it can be disproportionate, depending on how many people go through the system, to have this comitology where you have to have you chairing a committee of all the Member States looking at what seems to be a long list of things from prescriptions through to individual cases and medical technology and so on. Is that proportionate and not duplicating other things that you are doing?

Commissioner Vassiliou: You are talking about this chapter which speaks about co-operation in their disputes, I suppose.

Q385 Lord Lea of Crondall: Well, it is Article 5 and it is explained in Chapter 4 of the memorandum, 8.2, 8.3 and 8.4. There is a very considerable amount of things to do there when we have the impression that this might not be such a big deal that requires, and justifies, all of that.

Commissioner Vassiliou: It may not be a big deal for the UK or it may not be a big deal for Germany, but you have standards, you have quality and safety standards and you have your rules, and I do not want to mention countries, but we know very well that some Member States do not have standards and rules, so what we want to secure is the security of our patient when he or she decides to go to country B or C and that there are standards and rules in force. Even with the comitology, we are not telling Member States what standards they should impose, but we are asking Member States to just confirm to us that they have standards and that they will abide by these standards. That is all we want them to do. We are not harmonising the systems, but it is how we are going to protect our citizens and we know very well that, if we let them go without any information, without security and guarantees about the standards, they may accuse us later of not protecting them, so that is why we want to go into this procedure, which may sound complicated in the beginning, but it will save us from a lot of trouble at a later stage, we believe.

Chairman: I think we are going to find that there are all sorts of other questions about follow-up and we will come to some of those later on, but one big question is equity and, Lord Wade, you are going to take us into this area.

Q386 Lord Wade of Chorlton: Good morning, Commissioner. We have heard, in much of the evidence, of concerns about the issue of equity and I would like to ask you two questions on this matter. First, how can the inequity of the provision for payment upfront be addressed? What do you think of...
a system where payment is transferred directly between the healthcare providers in the Member State of affiliation and the Member State of treatment? In answering this question, I would be grateful if you could comment on what you think would be the role of private healthcare plans and healthcare insurance in dealing with these issues?

**Commissioner Vassiliou:** What we are saying regarding reimbursement in the Directive is that the patient will be reimbursed for treatment received abroad. What we want to make sure of with that is that payment will be made after the treatment is received and not before, but we in no way prevent any Member State from deciding to come to an agreement with foreign health providers to make payment directly without asking the individual to make an upfront payment; this is not our intention. Our intention is that payment will be after the treatment received. It may be that, in some cases, Member States may decide that they do not want to make direct payments, so the individual may have to pay and then be reimbursed. That is what the Directive is saying. We do not want to make direct payments, so the individual to make an upfront payment; this is not our intention. Our intention is that payment will be made after he receives the treatment. It may be that, in some cases, Member States may decide that they do not want to make direct payments, so the individual may have to pay and then be reimbursed by his Member State, or the Member State may decide that they would like to make direct payments. It may be that, in some cases, Member States may decide that they do not want to make direct payments, so the individual may have to pay and then be reimbursed. What we are saying regarding reimbursement in the Directive is that the patient will be reimbursed for treatment received abroad. What we want to make sure of with that is that payment will be made after the treatment is received and not before, but we in no way prevent any Member State from deciding to come to an agreement with foreign health providers to make payment directly without asking the individual to make an upfront payment; this is not our intention. Our intention is that payment will be made after he receives the treatment. It may be that, in some cases, Member States may decide that they do not want to make direct payments, so the individual may have to pay and then be reimbursed by his Member State, or the Member State may decide that they would like to make direct payments. It may be that, in some cases, Member States may decide that they do not want to make direct payments, so the individual may have to pay and then be reimbursed.

**Q387 Lord Wade of Chorlton:** That obligation would apply to the healthcare insurer, would it, the insurance company?

**Commissioner Vassiliou:** Yes.

**Q388 Lord Wade of Chorlton:** That it is illegal and they would have to pay?

**Commissioner Vassiliou:** Yes.

**Q389 Lord Wade of Chorlton:** The next question is: what do you think the impact of the proposal will be for patients in Member States where healthcare costs are less expensive than in many other Member States, and how do you think the potential inequity of this matter can be addressed? You did refer to this issue when you were replying to Lord Lea.

**Commissioner Vassiliou:** This is a more delicate question, and I want to acknowledge that there are many inequities and inequalities even now around Europe and there will be inequalities, not created by the Directive itself, but there are inequalities. If you compare the old Member States and the new Member States, there is a difference in the cost of living, in their healthcare costs, et cetera, so it would be difficult for patients living in the Eastern European countries to come to the Western European countries because they would have to pay the extra money themselves, so we acknowledge that there are inequities. Independently of the Directive, the Commission is coming up with a communication this year for a Council recommendation together with Commissioner Spidla to face the problem of health inequalities in Europe because it is a general problem and we acknowledge that. Moreover, we have decided to allocate €5 billion from the Structural Funds specifically to go to weaker Member States to be used for building up their health infrastructure, for training their healthcare providers, for teaching their personnel, et cetera, so, with all these measures which are independent of this Directive, but because we know there are these inequalities, we believe that eventually we shall reach a stage when the inequalities will be balanced. Moreover, we believe that, with the provisions that we have in the Directive for co-operation in the various fields, there will be a well-intended competition between healthcare systems which will drive them to improve their health systems. This will be, I believe, the indirect profit, benefit, of this Directive.

**Chairman:** I would like to move on to communication and the difficult issue of prescriptions.

**Q390 Baroness Neuberger:** Good morning, Commissioner. I have to declare an interest and you have made very clear why. I am appointed by the Irish State as a non-executive director of Voluntary Health Insurance in Ireland which has to do with all these nightmare issues at the moment, but my particular question is about the mutual recognition of prescriptions, which you have already alluded to. We have been told, in evidence we have received, that quite a lot of confusion can occur between Member States because of identical brand names being used in some Member States applying to different generic drugs, and that is already an issue with parallel imports, so I wondered how you thought actually that this could be dealt with. How important do you think that the mutual recognition of prescriptions is in cross-border healthcare and how do you think that obstacles to patient safety can be overcome? There is a further issue which you might want to comment on which is that, with the increasing use of e-health and people getting their prescriptions by email across borders, how is that going to be sorted out as well?

**Commissioner Vassiliou:** Let me remind you that the mutual recognition of prescriptions is not invented by this Directive.
Q391 Baroness Neuberger: Exactly.
Commissioner Vassiliou: There is a rule which already exists and very often we have problems in applying this rule because, as you quite rightly pointed out, there are confusions, there are doubts as to the authenticity of the prescription, of the signature of the doctor and so on, so what we are aiming for with this Directive is to agree on certain rules which will facilitate the exercise of this right of mutual recognition and to make it easier for people to do so, for example, common templates for prescriptions so that it does not need to be handwritten, but you have ticks in the appropriate places, etcetera. We have put it there because we want to adopt rules through comitology to facilitate the exercise of this rule. Now, regarding prescriptions through the Internet, it is up to the Member States to decide whether they will allow it or not and we do not want to harmonise this right because it is up to the Member States to decide. I agree with you that it is rather dangerous for prescribed medicines to be done through the Internet and, when we discussed recently the big package on pharmaceuticals, this was one of the points where we expressed real doubts as to whether we could allow it and that is why, for example, in the information package, we have put that information has as a rule to be prior approved and websites are registered with the authorities prior to launch so that it will protect the patient.
Chairman: Not only is there confusion about the names of prescriptions, but there is the whole issue about language, and Lady Gale is going to follow up on this now.

Q392 Baroness Gale: Good morning, Commissioner. I know you will appreciate the problems of the language barriers that exist, so how does the Commission consider that linguistic barriers can be overcome in order to deliver effective cross-border healthcare, and on whom do you think the responsibility should fall for any interpretation and translation?
Commissioner Vassiliou: Let us face it, this problem exists. I know, as a Cypriot national, that many Cypriots come here for treatment and I know that they find it difficult. They need somebody to accompany them, to explain to them, to be with them. Yes, it is a problem which exists and, with 27 Member States, the problem is becoming more acute, but we believe that this responsibility is not for the Member State of treatment, it is not up to the health provider. We cannot possibly demand the health provider to be responsible for the interpretation. If interpretation is needed and they pay for it, then it should be added to the cost and be paid either by the Member State of the patient or the patient himself or herself.

Q393 Baroness Gale: So there is no clarity on this at the moment?
Commissioner Vassiliou: It is up to the Member State to decide to what extent they can offer interpretation, but I think it is too much to ask the provider of the healthcare to be responsible for the interpretation.

Q394 Baroness Gale: So this could be a really big problem, I think, because it is quite costly, translation and interpretation.
Commissioner Vassiliou: It will be one of the factors that the patient always takes into consideration when he decides to go abroad, and I know very well that many people want to go abroad and have an operation, but this is one of the factors that holds them back and that is why we have such a low incidence of cross-border healthcare, it is one of the factors.

Q395 Chairman: People actually prefer to be at home.
Commissioner Vassiliou: At home in their own environment where they speak their own language and they have their own traditions, yes.
Chairman: And, if they do go abroad, there is the possibility of harm, and Lord Inglewood is going to pursue the definition of “harm”.

Q396 Lord Inglewood: Commissioner, obviously from time to time, regrettably, things go wrong in medical treatment and there is an approach in the Directive to establish a system for right to redress. The definition of “harm” is “adverse outcomes or injuries stemming from the provision of healthcare”, which is quite widely drawn. It has been suggested to us that that definition might be better slightly more narrowly drawn and that, for example, it would apply only to avoidable harm rather than accidental harm. What is the Commission’s attitude to that suggestion which has been made to us?
Commissioner Vassiliou: Certainly our intention is not to cover unavoidable harm. I know that there is this concern and we have no hesitation in accepting a wording which will clarify this because this is not our intention.

Q397 Lord Inglewood: That is most helpful, thank you. It follows that, in the event of there being unavoidable harm, presumably the law of tort in the country concerned would be the relevant law for anybody who wished to pursue redress in that way, so you would have two parallel systems of redress, one under the Directive and the other would be using the legal system of the country concerned. Is that right?
Commissioner Vassiliou: Well, the Directive sets the basis to establish the right of the patient to have redress, but it is not involved in the conflict of laws...
question. The law which will apply will be the law of the country of treatment.

Q398 Lord Inglewood: In all cases? Commissioner Vassiliou: Yes.

Q399 Lord Inglewood: So that, in turn, could be a considerable complicating factor in the event of something going wrong. Commissioner Vassiliou: That is why we have, in the Directive, a provision which states that one bit of information to be given to the patient is what procedure is to be followed in the case of some harm being done during the treatment. Chairman: This being a complex Directive, we are thinking about review, and Lord Cotter is going to follow up on the question about review.

Q400 Lord Cotter: Good morning, Commissioner. In this connection about the review, in our inquiry, many questions have been asked about patient inflows and outflows that will follow from the Directive, and there are many other complications, problems and difficulties as well. What is your view on the importance of the information for Member States and the planning, and safe, sustainable delivery, of healthcare across the EU? Do you think it would be useful for information on these flows to be included in the Commission’s Report, when it happens, and, given the uncertainties about the impact of the Directive, might the Commission report earlier than five years, do you think? Commissioner Vassiliou: Well, we have considered that the collection of data is very important because certainly, I believe, this Directive has to be reviewed at some stage because it is a difficult Directive and, through practice and data-collection, we will be able to improve things in the future, so it is very important for us to have a good system of data-collection. For the time being, when we did our impact assessment, for example, and we were requesting data from Member States, the data we received was incomplete, fragmented and not comparable, so we needed to ask Member States to include their collection of data in their existing systems of data-collection so that we have uniform data from all Member States. Now, why five years? Five years, we thought, was a reasonable time for the Directive to be fully developed after the comitology procedure and all of this so that we could have reliable data from the Member States and, once we have received reliable data, then we can all make up our minds whether it needs revision and on what aspects. Mr Merkel points out to me that it is “within” five years, but we say that, in five years’ time, we believe it will be fully developed, although we have no objection, if Member States believe that it should be earlier, to doing it at an earlier stage.

Q401 Chairman: It does seem that what would be useful is maybe feedback as the Directive develops because, in talking with our own Minister, we discovered that there was very little information about patients travelling abroad for authorised, never mind other, treatments, so, even in the UK, when you think you may have sophisticated systems, you will find that we are not going to be able to provide very good data at this moment in time, so, as that develops, I think countries would find it extremely useful in the understanding of inflow and outflow and how things are developing. We note that the Commission consulted widely, that your initiative began as long ago as September 2006, and we are really interested to know a little more about how the initial consultations were conducted, which stakeholders were invited to contribute and how the Commission consulted on the legislative proposal generally. It is just that we were rather interested to know where you were getting your information and views from, and certainly some of our witnesses felt a little unheard. Commissioner Vassiliou: I have here an extensive list of what we have done, so can I please consult my notes on this because, as you know, I am rather new in the job? Historically, it is a very long list of consultations.

Q402 Chairman: Commissioner, it would be very welcome if you wanted to send us your list rather than read the whole list. That is perfectly acceptable for the Committee to receive it as a written list, so long as you could give us a general view about the width. Commissioner Vassiliou: We have consulted all stakeholders, for example, patients’ associations, doctors’ associations and NGOs, who deal with questions of health. We had consultations with the European Parliament. They had issued two reports on the specific issue of cross-border healthcare especially after 2006 when initially, as you know, they had provisions in their Service Directive and, when they started discussing it, they preferred to take it out, and quite rightly I believe, and asked the Commission to have a separate Directive taking into consideration the specificities of healthcare. After they decided that, they had an extensive debate on that and we had two reports from the European Parliament on that. Also, we have had up until now several consultations with health ministers during
both the formal and informal Council meetings, the last one being the Council meeting under the French Presidency in Angers where we had an extensive consultation with ministers on that. I will send you this list, but this is, in a nutshell, what we have done, and also we have consulted external experts who have made a study on the issue, the European Observatory on Health Systems and Policies. They were our consultants in advising us on this issue.

Q403 Chairman: Unfortunately, the person we had hoped to come and give some information about the parliamentary response was not able to come and give us evidence, so we are doubly grateful to you because we had not managed to speak to him.

Commissioner Vassiliou: There is one more point which is that, when we opened up this public consultation, because we also had a public consultation, we received 280 responses from various stakeholders, so these, for us, are very valuable because each one of them had an experience on cross-border healthcare.

Q404 Lord Wade of Chorlton: In one of your replies, in fact when speaking to me, you mentioned that you hoped that this system would slowly level out and improve the standards of healthcare throughout the whole of the EU. I have no experience of healthcare outside this country, but are there very wide differences in healthcare throughout Europe and is what you are suggesting likely to be difficult to achieve or easy to achieve, to get a general improvement in the standard across Europe?

Commissioner Vassiliou: Well, my answer to your question is that, yes, there are many different standards. There is of course scope for improvement and that is why we are aiming to adopt several measures to try to balance the quality of health treatment, but we believe honestly, with this cooperation that Member States will have under this Directive, that we will have improvement in all Member States because I see now the eagerness by which health ministers are starting to look at the various aspects of their healthcare and have started already making plans of how to improve there, so indirectly we have this effect as well. I think one of the additional benefits is in the field of rare diseases. I do not know if you know, but there are 7,000 rare diseases in the European countries nowadays. We have a specific Communication and proposal for a Council Recommendation on rare diseases, but it is impossible for each Member State to organise its healthcare system in such a way as to provide for all these rare diseases, so we want to encourage cooperation in this field of rare diseases so that, if there is a centre for excellence for a particular rare disease in Austria, why not use that centre instead of every Member State going into the huge expenditure of organising the specific healthcare themselves, so this will be really added value.

Q405 Chairman: Commissioner, we really have run out of time now, but, as you know, we did learn a lot in our organ donor inquiry from other countries and, I think, managed to influence our own Government significantly through that Report in what our task force is now undertaking, so I hope we can show a light and I hope that, when our Report is produced, you will find it helpful and useful in your further deliberations. That of course will be a Report to our Government, but we will send you a copy directly, as we have done with our other reports. Again, can I thank you very much for joining us. Unfortunately, I have to be on the floor of the House in five minutes and, therefore, do not have the pleasure of seeing you out, but we do have the Chairman of the Select Committee, Lord Roper, sitting with us today and we are very grateful to him for joining us. I apologise that, unfortunately, I have to be in a debate and the rules say I have to be on the floor of the House at the beginning of the debate.

Commissioner Vassiliou: Let me say, it was indeed a great pleasure for me to be with you today and I hope I have been helpful with what I have said.

Q406 Chairman: Very helpful.

Commissioner Vassiliou: I have enjoyed our dialogue and I am sure your Report will be of great help to us. Thank you very much.
Supplementary memorandum by the European Commission

Consultation

The Commission’s formal consultation on this initiative began in September 2006 and a summary report of the responses can be found on the Commission’s website.¹

Q12. How was the Commission’s initial consultation on this initiative conducted, which stakeholders were invited to contribute and how has the Commission consulted on its legislative proposal?

— Stakeholders have been extensively involved in Commission activities regarding patient mobility and healthcare over many years, in particular through the High Level Reflection Process, the Open Health Forum and the High Level Group on Health Services and Medical care.

— Consultation on the specific initiative on cross-border healthcare started formally in September 2006 with the publication of a Communication regarding Community action on health services. The Commission received 280 responses to this consultation from a wide range of stakeholders, including health professional organisations, health care providers, national and regional governments, insurers, the industry and individual citizens.

— This proposal is also based on several external surveys, analyses and studies conducted in the past years. In particular, the European Observatory on Health Systems and Policies provided an independent expert analysis, which was used especially in support of the impact assessment of this proposal.

— The European Parliament also contributed to the discussions concerning cross-border healthcare with various reports. The Parliament adopted in April 2005 a report on patient mobility and healthcare developments in the European Union; in March 2007 a resolution on Community action on the provision of cross-border healthcare; and in May 2007 a report on the impact and consequences of the exclusion of health services from the Directive on services in the internal market.

— Finally, the Member States were also consulted extensively. The Council adopted in June 2006 conclusions on Common values and principles in EU Health Systems in which it stated that it believes there is particular value in any appropriate initiative on health services ensuring clarity for European citizens about their rights. Prior to the adoption of this proposal, these issues were discussed at length with the health ministers at several occasions by my predecessor Commissioner Kyprianou as well as myself, including at the formal and informal Council meetings.

January 2009

¹ http://ec.europa.eu/health/ph_overview/co_operation/mobility/results_open_consultation_en.htm
Written Evidence

Memorandum by the Association of British Insurers (ABI)

INTRODUCTION

1. The ABI is the voice of the insurance and investment industry. Its members constitute over 90% of the insurance market in the UK and 20% across the EU. They control assets equivalent to a quarter of the UK’s capital. They are the risk managers of the UK’s economy and society. Through the ABI their voice is heard in Government and in public debate on insurance, savings, and investment matters.

2. The insurance industry welcomes the European Commission’s efforts to ensure that patients’ rights within the European Union are improved by establishing a general framework for the provision of safe, high quality and efficient cross border healthcare. This note represents the ABI’s preliminary viewpoint, as our consultation with our members is not yet complete.

3. Our assumption is that the primary purpose of the Directive relates to State provided healthcare, and the Directive covers the “insured person” as defined by Regulation (EC) No 883/2004. One interpretation is that PMI, as operated in the UK market, is not therefore included however, the Directive and Explanatory Memorandum refer to private funding. We need clarity concerning whether the Directive applies to healthcare that is funded privately, in particular through a private medical insurance policy. There could also be implications for health cover within Travel insurance.

GENERAL COMMENT

4. The private medical insurance industry in the UK operates in a different way to other EU Member States’ health systems by operating a duplicative system in parallel to the national health system (with the exception of accident and emergency treatment and the long-term management of chronic conditions). This is in contrast to many other EU Member States where consumers buy private medical insurance to complement or supplement their national health system cover.

5. The draft Directive sets out that a patient travelling to another Member State with the purpose of getting healthcare should be reimbursed up to the level of costs had the same/similar healthcare been provided in their Member State.

6. There is a lack of clarity concerning whether the Directive explicitly applies to private medical insurance as a funder of healthcare. Article 2 states the Directive will apply to the provision of healthcare whether it is publicly or privately funded. The Directive also contains a definition for an insured person and reference to Regulations 1408/71 and 883/2004, which refer to an insured person and their affiliation to a national social security scheme, not to a private medical insurance scheme. British insurers need clarification on this matter. We are also consulting with the industry on the implications of being either included or excluded from the Directive.

7. Should the scope of the Directive include private medical insurance, the arrangements for prior authorisation would be very important to us. Insurers need to retain adequate control of the circumstances in which patients can take advantage of their right to seek medical treatment anywhere in the EU. This is for the safety and health of patients concerned, and to ensure the costs for all insured parties can be managed. We would also take a close interest in the definitions of hospital and non-hospital care, the authorisation of prescriptions, the information provided to patients if harm were to be caused, national contact points and the reliability of the proposed data to be collected.

8. It is important that the authority given to Member States to determine the mechanism for patients to seek redress and compensation if they suffer harm, as a result of receiving cross border healthcare, is retained. The insurance industry supports this flexible approach given to Member States and the recognition by the European Commission that such arrangements should have regard to the guarantees that are already in place.

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1 Explanatory Memorandum states at p7 this “is the case no matter how the care is paid for—whether it is paid for publicly or privately” and at p11 confirms the freedom of Member States to organize their health systems with specific mention of the use of personal contributions and supplementary insurance. Article 2 of the Directive states it, “shall apply to provision of healthcare regardless of ... whether it is public or private”.
in the healthcare provider’s home state. The industry was opposed to earlier proposals for a compulsory liability insurance scheme.

9. The industry seeks to ensure the Directive would not increase insurance costs that would be passed onto consumers by way of increased premiums. In order to avoid this, the Directive should allow insurers to continue to:

(a) Manage policyholder access to treatment regarding:
   — The extent of medical cover, including pharmaceuticals.
   — Prior authorisation. Consumers with private medical insurance must always obtain prior authorisation when receiving medical care.

(b) Restrict additional services and administration costs:
   — The provision of information services and administration for patients, such as overseas payments and currency transactions, should not be allowed to raise costs unnecessarily.

ABI RESPONSE TO THE QUESTIONS OF THE SELECT COMMITTEE

What do you see as the general advantages and disadvantages of patients having the right to obtain healthcare in Member States other than that where they reside?

10. The general advantages are:

(a) The ability for a patient to access treatment they are entitled to receive in their own country in good time.

(b) Greater access to cross-border healthcare could increase the availability of affordable new treatments and improve access to Centres of Clinical Excellence.

(c) The possible development of insurance products tailored for those consumers who are prepared to travel aboard for treatment.

11. The general disadvantages are:

(a) Responsibility for follow-up care is unclear. The Directive comments on patient entitlement to compensation but does not clarify the funding responsibility for further clinical intervention to follow up on overseas treatment or health problems.

(b) Where prior authorisation is not required or indeed requested, patients could be left with significant debt if there were a shortfall in funding for treatment that exceeded their entitlement in their home state.

(c) Patients would be responsible for the cost of travel and repatriation, with the exception of those within the social care system of the Member State.

(d) There may be an increase in the number of patients who seek treatment in another state because their home state does not provide that treatment. This will give rise to challenges about whether or not their home state should provide that treatment. One current example is new cancer drugs.

In what circumstances might patients seek to exercise any such right?

12. Patients could seek healthcare abroad to access treatment that was available within another the Member State; but was:

(a) Not available within a clinically acceptable timeframe in their own Member State; and/or

(b) Not funded by the patients’ Primary Care Trust.

We recommend that limits be put on treatments that are not licensed and/or are experimental.

What problems do you think have arisen as a result of the present uncertainty in respect of EU citizens’ rights to obtain such cross-border healthcare and to have the costs of this reimbursed by the Member State where they reside?

13. EC Regulation 1408/71 and the European Health Insurance Card (EHIC) entitlements are not universally applied across Member States. Some UK patients with travel insurance were:

(a) Advised either that there was no available state funded healthcare or there was an excessive waiting list, for example of six months and the only option was to use private healthcare facilities.

(b) Unable to meet the administrative requirements of claiming reimbursement under the EHIC.
We submit that all Member States should recognise the intent of the EHIC and not erode State entitlements merely because alternative funding might be available from Travel insurance or a supplementary insurance product.

14. There is a lack of clarity for patients. Patients need access to adequate information about available healthcare options, what treatment they could seek based on what their home state would provide, security around sending confidential medical information over the internet, and the process for obtaining finance for the treatment either up front or in reimbursement.

15. There is a need to address the issue of access to cross-border healthcare but with the strong caveat that it does not impose any increased costs on the private medical insurer or funder of the healthcare. There is a distinction between removing barriers to accessing healthcare and facilitating access to the extent that it undermines individual Member States’ healthcare systems.

16. We recommend further clarification from the Directive in the situation where responsibility lies for patients who have healthcare entitlements in more than one Member State, that is:

(a) For a patient who has moved temporarily to another Member State.
(b) Where there is double insurance or two or more potential funders.

17. The Directive infers that the patient would make up any shortfall between the cost the Member State would fund and the actual cost of the healthcare. We recommend the Directive clarify how the cost of pre-authorised healthcare would be determined. For example, if an average cost is taken from a diagnostic related group the actual cost could be greater.

18. Under the Directive prior authorisation can be given for “hospital” care but not for healthcare provided in a “non-hospital” setting. The use of facilities to denote the complexity or seriousness of a treatment does not take account of:

(a) The increasing use of day patient and out patient treatment.
(b) The different use of healthcare facilities across the EU.

We recommend that prior-authorisation be introduced into the Directive according to the treatment required and not the medical condition nor the facility used to provide the healthcare.

19. Patients should only receive State funding for treatment that is accessible to patients in the Member State.

20. Member states must be able to manage patient treatment and control costs through pre-authorisation. This should be the rule not the exception. We recommend the onus should be on a timely pre-authorisation process rather than a post-reimbursement process where patients may find themselves out of pocket if they receive treatment their home state does not consider it should pay for.

21. The cost of treatment sought in another Member State should not exceed the cost of the same treatment in the patient’s home state and should not undermine contractual scope and pre-authorisation arrangements between insurers and customers. Clarity is needed on the requirement for a home state to provide or fund “medicinal products” to continue a patient’s treatment that commence in another member state.
What is your view of the likely practical impact of the proposals and of how they would affect day-to-day healthcare provision in the UK? For example, could language difficulties present an obstacle?—Who should be responsible for after care (out-patient and in-patient)?

22. Without a clear definition of treatment the scope of the proposed Directive could be open to dispute.

23. The UK health system could become more complex. The health budget is set at a national level but managed locally. This gives rise to differences in the availability of treatment between Primary Care Trusts that are already subject to challenge by patients. The complexity would increase where patients “compete” for funds by travelling to another member state for treatment.

24. Interpreter and translation services would be required for patients, clinical staff and the healthcare provider and funder. This would include translating the medical history and new medical notes to ensure appropriate follow-up care.

25. Exchange of patients’ medical information between Member States could be complex both from a security perspective and due to language difficulties.

What is your view of the need to limit the medical conditions for which treatment could be sought in this manner?

26. If any limit on medical conditions restricts access to goods and services, the implications of the Disability Discrimination Act should be considered.

What are your views on the provisions set out in the draft directive for cooperation between Member States, including: the mutual recognition of prescriptions; the establishment of European reference networks of healthcare providers; e-health; and the management of new health technologies?

27. The mutual recognition of prescriptions assumes that if drugs are EMEA licensed and they are available in all Member States it is only the authenticity of the prescription that needs to be checked. We recommend the Directive clearly states what exclusions would apply.

October 2008

Memorandum by the Faculty of Pain Medicine of The Royal College of Anaesthetists

1.1 The Faculty of Pain Medicine of the Royal College of Anaesthetists is grateful for the opportunity to respond to this Inquiry. The response is limited to three questions only.

Question 1. General advantages and disadvantages

2.1 Most patients with chronic pain or cancer pain require medication to control their pain. Sometimes the medication is a strong opioid drug and this will present a problem during travel if there are different regulations in different countries. It might be advantageous to allow patients to obtain repeat prescriptions in other European countries on a short term basis but this would present a major challenge for the prescribing doctor in confirming that the patient was (a) entitled to the drug and being appropriately treated and (b) not exhibiting signs of drug abuse or addiction.

2.2 There are some patients with chronic pain or cancer pain who have implanted drug delivery systems or implanted stimulators (eg spinal cord stimulator). These devices are both expensive and complex. It would be advantageous if these patients could receive continuing care if they travelled in Europe but, on the other hand, a major disadvantage would be the arrival in the UK of patients who have had these devices implanted in other European countries and who then seek to have their care continued in the UK.

Question 7. Practical impact

3.1 Language certainly presents a problem in the management of non-English speaking patients who present to UK pain clinics with chronic pain. Chronic pain is a complex multidimensional condition and its assessment involves a lot of detailed questions. Consultations conducted through an interpreter are rarely satisfactory. For some patients the optimal treatment involves a cognitive behavioural pain management programme and patients cannot participate in such a programme in the UK if they cannot speak English well.

2 Directive page 19—8.2
3 Directive page 20—8.6 and page 41 14.1(a)
Question 8. Limiting medical conditions

4.1 Patients with chronic pain go to extreme lengths to obtain help and travel from centre to centre seeking a solution to what may be an insoluble and intractable condition. Also, some patients are liable to seek out practitioners who gain publicity or make great claims for their particular therapeutic approach even though these claims for efficacy (and safety) are not supported by scientific evidence. It would not be desirable to encourage patients to seek help for chronic pain in other European countries unless this is for clinically proven treatments that cannot be obtained in the UK.

24 September 2008

Memorandum by Richard Fowler

1. This is a patient’s/citizen’s perspective. As a private UK citizen I have been tracking aspects of EU Regulations 1408/71 and relevant directives etc for over 10 years. The central issue is the extent to which the state or the individual EU citizen controls access to healthcare. Cross-border healthcare is just one aspect but young and old increasingly see themselves as European citizens and are frustrated by political or bureaucratic foot-dragging.

2. I have three main concerns:

   2.1 Without a major shift in Department of Health (DoH) attitude and policy at ministerial level, very few UK citizens will benefit from the proposed Directive. Maintaining the status quo means routine obstruction and refusal.

   2.2 Key negotiations over the proposed cross border healthcare directive exclude citizens.

   2.3 The UK’s “opt-outs” from parts of the Lisbon Treaty (Fundamental and Human Rights) seem to allow the UK to negotiate a directive to which they are not bound also to shield the UK authorities from Human Rights provisions where death, injury etc arise from healthcare policies.

3 What prompted me to take an interest in the first place was realisation that I or people I knew might need to rely on EU Regulation 1408/71 either to travel (Article 31) or because of long waiting lists for NHS treatment (Article 22).

   3.1 Article 31 allowed OAPs and the disabled (broadly groups with existing health problems), most of whom cannot get travel health insurance at all or at an affordable price, to visit Europe (for up to 90 days) without fear of penury. Article 31 was subsumed into, and extended by Regulation 631/2004.

   3.2 Article 22 covers both emergency healthcare and travel to another EU Member State for treatment. The latter is subject to prior authorisation by the home state (which is required to pay) but importantly, the home state cannot refuse authorisation where there is undue delay in treatment. At an individual level, this should limit patients’ pain or risk of death, but collectively it exerts pressure on the DoH and NHS to improve waiting times, quality and funding. In moderation, this is a positive effect of subjecting patient choice in healthcare to “market” conditions. As recently as March 2008 UK minister Ben Bradshaw referred in a BBC radio 4 interview to the 1990s “when thousands were dying on waiting lists”.

4. However I discovered that while some rights under Reg 1408/71 (eg Article 22.1 emergency treatment, the “E111”, now EHIC) worked fairly well, the two key rights to non-emergency healthcare under Articles 31 and 22.2 (the “E112”) did not. What maintained my interest was the further realisation through contact with the (then) EUs Health and Social Welfare DG and the DoH International Branch that this was not accidental and was politically sensitive.

   4.1 Specifically the UK policy of “discouraging medical tourism” deliberately and effectively undermined patients’ rights and the EU appeared to be well aware of this. Apparently some other EU member states (eg Netherlands; Greece) also prioritised their national healthcare rules over Reg 1408/71 to similar effect.

5. This policy seems to be inconsistent with lofty EU aims and operates in diverse ways. For example:

   5.1 The official DoH information (Booklet: Advice to Travellers) for over 20 years failed to tell OAPs and the disabled of their enhanced rights under Reg 1408/71 Article 31. In 2002 a newspaper reported the case of an 81 year old Scot faced with losing his home after his angina worsened while
in Spain and his travel insurer refused to pay because of non-disclosure. Knowledge of Article 31 should have enabled him to significantly reduce the cost.

5.2 Reportedly, the UK got the previous EU Health Commissioner to approve the UK procedure for handling requests for authorisation for treatment in another EU Member State (E112). Involvement of the EU Commissioner in this way is questionable. This convoluted and time-consuming procedure is a delay and a deterrent in itself and incorporates financial aspects which may not accord with the Commissioner’s understanding at the time. The financial criteria seem to have evolved over 10 years from a high-level failsafe “not upsetting the financial equilibrium of the state” through “not exceeding the healthcare budget” to “best use of resources (in individual cases)”.

5.3 The only route of appeal against refusal of authorisation is a Judicial Review taking months and costing tens of thousands of pounds. This is stated clearly in the DoH Booklet Advice to Travellers and on the website.

6. The friction arising from these restrictive practices is indicated by the cases eventually taken to the European Court of Justice (ECJ) and the low number of E112s issued. The UK issues 400–500 annually averaging about two per PCT/Health Board or about 1:120,000 people. In comparison Sweden issues about 1,000 or 1:8,000 people.

7. In my view, in the UK, the driving force behind this opposition to genuine patient choice including on cross border healthcare appears more than concern for proper planning and management of healthcare resources. There appears to be firstly a dogmatic belief that the rich and articulate will exploit the directive and steal resources from the poor. Secondly a deep rooted culture in which health is not provided as a vital public service but exploited for political advantage which subordinates the patient/citizen to most other stakeholders. This manifests in hostility to allowing UK citizens any real control over their healthcare, the latter being normal elsewhere in the old EU.

8. The EU is obliged under international trade etc agreements to open public services to competition (hence increasing private sector involvement in public healthcare provision) but healthcare was kept out of the Services Directive because of its special status.

9. The original draft cross border healthcare directive was a radical move to almost unlimited patient choice. Some EU Member States felt that a market driven, patient-centred free-for-all could cause shortages or overstretch with potentially serious effects on society and public health. The first revision to the draft maintained significant patient choice but capped at 1% of a country’s patients before prior authorisation could operate. To put this in context this could be say 50,000 to 200,000 UK citizens—depending on how counting is done—per year compared a few hundred now. In my view, with some refinement this would have been a reasonable compromise, generally distancing the state from individual healthcare decisions but retaining overall control.

10. However the draft directive adopted in July 2008—without public consultation it seems—reintroduces prior authorisation—in theory as a longstop—and creates a major “get-out” clause (planning, training, etc). However on past performance there is a risk that behind the scenes moves will re-establish routine and restrictive prior authorisation to maintain the status quo as far as possible. This shifts control back to the state. In 2008, referring specifically to the proposed cross border healthcare directive, UK Health Minister Dawn Primarolo and a former Health Minister were both reported in the press to the effect that “the NHS will decide who is treated where”.

11. There is a question mark over the UK’s involvement with this directive at all. The UK “red-lines” “opt-outs” “protocols” etc in the Lisbon Treaty mean that the UK did not agree to be bound by aspects of the Charter of Fundamental Rights and specific Human Rights provisions upon which the proposed directive is based. Therefore the question arises as to whether the UK should be involved in negotiating a directive which it can perhaps just ignore if it suits. The further question is whether in these circumstances domestic or international Human Rights law could limit the UK’s freedom to make health policy decisions which result in death or injury. Finite resources inevitably mean that governments make life or death choices but the criteria and methods involved in reaching those may be subject to scrutiny.
That concludes my main points of concern. The following sections 12 to 21 add points I feel relevant to the prompts in the Call for Evidence:

12. Pros and cons of cross border healthcare;
More and more EU citizens move between EU/EEA Member States. Please bear in mind that half a million plus EU citizens eg Poles have been working in the UK and acquiring rights through NI contributions, yet not contributing in their country of birth. They may work in the UK but may not unreasonably wish to return to family during significant treatment.

13. Effects of present Uncertainty
Choking of demand. Confrontation and stress when a patient is vulnerable, when help and support are needed.

14. EU involvement and objectives
Reciprocal agreements outside the EEA/EU including with the so called “A8” (mainly Eastern European Accession States) were a hotch-potch suitable only for small numbers of people. With 500 million EU citizens potentially on the move there is a pressing need for a better system and the only suitable organisation to arrange it is the EU.

“Clarity” is inadequate and a political fudge because the EU is debarred from promoting “harmonisation”. The citizen’s real need is for consistent high quality healthcare with some intelligible commonality of funding and procedures between countries.

15. Effectiveness of Proposed directive
This depends on whether member states approach the directive with a sense of cooperation or with self-interest in mind.

16. Restrictions on citizens rights to cross-border healthcare
Restrictions should be kept to an absolute minimum ie a “longstop” not case-management. It makes no sense to waste doctors and officials time and cost ponderously deciding whether one patient should have the same treatment in one hospital or another unless large numbers threaten to wreck the system. If a health insurance company decided it could offer budget cover by exploiting the directive, it could generate the sort of numbers of patients which might distort healthcare provision in a locality. Some travel insurers routinely require travellers to have an EHIC, presumably to limit claims. The EU commissioned research sampling healthcare costs which showed wide variation but broadly placed the UK among the “old” European norm. Cheaper Eastern European States could easily be swamped by large numbers of patients from wealthier states to the detriment of their own people.

17. Limits on Reimbursement
Limiting reimbursement to the cost of treatment in the home state is a fair system but there will be a shortfall of some sort so this will inevitably create a co-payments system which the UK has resisted officially, but which already exists at a low-level (dentistry, prescriptions etc).

Ideally, patients need access to national or commercial ‘top-up’ insurance to cover more of the shortfall.

18. Practical impact
N/C.

19. Limits on scope of medical conditions treated
A reasonable basis would be NICE approved treatments or nearest equivalent available in the Member State providing treatment.

This would allow patients to avoid a “postcode lottery” for NICE approved treatment refused by a PCT/Health Board but not for treatments not approved by NICE (eg some expensive cancer drugs).

20. Inequality of means or access
This appears to be the main source of opposition to the directive articulated by some political groups in Westminster and the EU parliament. This argument is being used to justify restrictions.

Cross border healthcare is not a problem for the wealthy and privately insured who can usually get the healthcare they want in the UK.
The poor and the “have-littles” would largely be excluded without help and the rest may struggle to varying degrees. I know a couple on the UK state pension who sold their home of many years and moved to a cheaper area to pay for private healthcare in the UK.

Perhaps the state systems could agree to provide the worst off with “top-up” insurance to cover a shortfall between reimbursement and total cost? Those with more money could buy such cover at reasonable cost? My cousin was faced with significant costs when her husband was taken seriously ill in France and eventually had to be returned to the UK where he died.

One aspect which needs to be addressed is the cost of medical repatriation and insurance to cover it. The real problem to be addressed is relative poverty. There was a hint that EU Commissioner Spidla would propose something in conjunction with the directive.

21. Access and information

A national information point is proposed. The official DoH booklet “Advice to Travellers” and website should also provide information nationally.

At a local level doctors’ surgeries, hospitals and local groups such as Citizens Advice or patients’ representatives groups could inform patients or direct them to national sources.

8 October 2008

Memorandum by the General Osteopathic Council

Key Concerns for the General Osteopathic Council (GOsC)

The GOsC welcomes a clear framework for cross-border healthcare which this proposal seeks to achieve, but this should not be at the expense of patient and public safety. In any future directive we will be calling for:

1. Support for the development and implementation of regulatory mechanisms across Europe to ensure a high standard of osteopathic care for patients, and

2. A Europe-wide approach to communication and information sharing (such as registration and fitness to practise data on healthcare professionals) between competent authorities.

Background to the General Osteopathic Council

The General Osteopathic Council (GOsC) has a statutory duty to regulate the practice of osteopathic care in the UK. Osteopaths must be registered with the GOsC in order to practise in the UK.

We work with the public and profession to protect and promote patient safety through effective regulation of osteopaths in the UK, by:

— registering qualified professionals;
— setting standards of osteopathic practice and conduct;
— assuring the quality of osteopathic education;
— ensuring Continuing Professional Development; and
— helping patients with concerns or complaints about an osteopath.

Website: http://www.osteopathy.org.uk

1. Balancing free movement with the maintenance of public and patient safety

— As both patients and healthcare professionals move increasingly within the EU, there is a need for greater patient protection through proper regulation and high standards of treatment. Whilst this draft directive seeks to ensure that the necessary requirements for high-quality, safe and efficient healthcare are ensured for cross-border care, we are concerned about its practical implementation. This is because of the diverse approach to access and quality of healthcare in and between Member States.

— Currently, osteopathy is regulated in only four EU Member States—Finland, France, Malta and the United Kingdom; and between these countries the systems of regulation differ. With the aim of promoting regulation in Europe, the GOsC initiated the Forum for Osteopathic Regulation in Europe (FORE)4 to help enhance patient protection and confidence in osteopathic professionals.
FORE brings together national registers and competent authorities across Europe to develop a consensus on benchmarks for standards of osteopathic education, training and practice. We hope, therefore, that with this proposal the European Commission will encourage Member State Governments to develop regulatory mechanisms for osteopathy where these do not currently exist.

— In any future directive, the GOsC will be calling for support for the development and implementation of regulatory mechanisms across Europe to ensure a high standard of osteopathic care for patients.

2. Consistency of information sharing between healthcare regulators

— The draft directive also sets out a duty of cooperation between Member States on cross-border healthcare. We would, however, go further to call for a more robust Europe-wide approach to communication and information sharing (such as registration and fitness to practise data on healthcare professionals) between competent authorities. This is not just so that the regulator is in a position to determine an osteopath’s fitness to practise, but also to enable the patient to know what they can expect from an osteopath, and to be assured a means of redress, should this be required.

— In this regard, we would welcome the formalisation of the agreements of the “Healthcare Professionals Crossing Borders”5 initiative which provide a framework to enhance cooperation between healthcare regulators in Europe.

— In any future directive the GOsC will be calling for a Europe-wide approach to communication and information sharing between competent authorities.

September 2008

Memorandum by The Law Society of England and Wales

1. The Law Society of England and Wales is pleased to submit this evidence to Sub-Committee G’s inquiry into the EU Commission’s proposal for a Directive on patients’ rights in cross border healthcare (“the proposal”).

BACKGROUND

2. This submission has been prepared by the Law Society of England and Wales (the Society), the representative body of over 135,000 solicitors in England and Wales. The Society negotiates on behalf of the profession and makes representations towards regulators and government in both the domestic and European arena. This submission has been drafted by the Society’s EU Committee, which is composed of practitioners with an expertise in this field.

INTRODUCTION

Important legal issues

3. The Commission’s proposal raises a number of important political and practical issues. In this submission we will concentrate on three important legal questions:

(a) the scope of the proposal—the question of vires or legal base (paras 8–9);

(b) making rights accessible—problems of definition (paras 10–14); and

(c) making rights enforceable—responsibilities and information (paras 15–18).

Importance of high level of health care—legal foundations

4. The Society notes, and supports, the importance placed by the Union on access to a high level of healthcare, both domestic and cross-border. This is evidenced by the EU Charter of Fundamental Rights, Community subordinate legislation and the jurisprudence of the Court of Justice.

5 Healthcare Professionals Crossing Borders (HPCB) is an informal partnership of professional healthcare regulators from within Europe that works collaboratively on a range of regulatory issues. The purpose is to contribute to patient safety in Europe through effective regulatory collaboration in the context of cross-border healthcare and free movement of healthcare professionals.
5. Article 35 of the Charter states:

“Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities”.

6. The Court of Justice has, in a series of cases, held that patients can rely on the fundamental principles of the Community, in particular the free movement of services, to obtain treatment in a Member State other than their home State.

A welcome proposal

7. When introducing the draft Directive on the application of patients’ rights in cross-border healthcare⁶, the European Health Commissioner Androulla Vassiliou said:

“This proposal aims to clarify how patients can exercise their rights to cross-border health care, while at the same time providing legal certainty for Member States and health care providers. It ensures that the quality and safety of health care will be guaranteed throughout the Union, and promotes cooperation between health systems to provide better access to specialised care.”⁷

Healthcare services⁸ were excluded for the (general) Services Directive 2006/123⁹; the subject is one involving both technical and political difficulties. The Society therefore welcomes this attempt by the Commission to clarify and simplify this area of Community law, which is of particular concern to European citizens. We support the Commission’s objective of removing any uncertainty in the present legal position, of reducing the administrative or other hurdles facing the patient seeking treatment in another Member State, of ensuring the standard of such healthcare and also redress where things go wrong (whether in the administration of the system or in the treatment itself). The draft Directive should strengthen and make more secure the physical and legal wellbeing of the patient.

Legal Issues

Legal base

8. While the title of the proposal is specific and, upon first examination, quite limited (“the application of patients’ rights in cross-border healthcare”) the content of the proposal is extensive with potentially far-reaching implications for Member States. The draft Directive would lay down Member State “responsibilities” (not necessarily restricted to cross-border cases) (Article 5) and would also provide for the development of European reference networks (Article 15), for E-health (Article 16) and for co-operation on management of new health technologies (Article 17).

9. The Commission bases its draft on Article 95 TEC, drawing attention to the express limitations of that Article as well as the principle of subsidiarity. The Commission rightly acknowledges the existence and the limitations of Article 152.¹⁰ Nevertheless the question needs to be asked, the Society submits, whether Article 95 provides a sufficient legal base for all that is being proposed. The Court of Justice has, when defining the scope of Community law based rights in this sector, been conscious of the competing policy interests, expressly recognising that the supply of cross-border healthcare should not jeopardise the need to safeguard domestic healthcare provision and social security systems.¹¹ “Health” is not excluded from being the subject-matter of Community legislation Article 95. But the existence, extent and limitations of Article 152 are, we believe, significant. The Community legislature should respect the respective competences of the Community and Member States as manifested in the different Articles of the Treaty. This is an issue to which we would expect the Government to pay special attention, especially given the potential financial implications for Member States.

⁷ Press Release IP/08/1080.
⁸ More particularly, Article 2 (2) excluded “(f) healthcare services whether or not they are provided via healthcare facilities, and regardless of the ways in which they are organised and financed at national level or whether they are public or private”.
¹⁰ See Explanatory Memorandum p 8.
The right to seek healthcare abroad and to be reimbursed in the Home State

10. The Law Society agrees with the Commission that there is lack of clarity over what Community law means in practice for cross-border health services. We note that the proposal is not limited to EU citizens but extends to all those “insured” under Member States social security/healthcare system.

11. The key question is whether the draft Directive is sufficiently clear as to the nature and extent of the right to seek healthcare abroad and to be reimbursed in the Home State and how it can be exercised. Various issues arise in relation to the scope of this right. For example, what is encompassed by the term “healthcare service”, used within the definition of “healthcare” (Article 4 (a)), should be clear, in particular the extent to which it includes the supply of medicinal products, prosthetics and other equipment as part of the treatment in question.

12. The definitions of “hospital and specialised care” and “non-hospital care” in Article 8 (1) are also of primary importance. The main distinction between hospital and non-hospital care appears to be the need for overnight accommodation. But the draft Directive (Article 8, read in light of recital 30) does not say whether such accommodation is because the treatment requires “in-patient” care lasting 24 hours, that the accommodation should be in a hospital or within “healthcare facilities”12, or even what is a “hospital” for these purposes. “Hospital care” presumably does not include the case where the patient has to arrange overnight accommodation in order to be able to attend the doctor for treatment. The Commission’s Explanatory Memorandum refers to a stay in a “hospital or clinic”.13 But what of the case where there is successive out-patient treatment over two or more days? The draft Directive could usefully clarify whether the accommodation should be in a hospital or within healthcare facilities.

13. A separate problem arises from the different approaches of Member States to the delivery of treatments. It is, for example, not uncommon to have day surgery (ie no overnight stay as a general rule) in the UK system. Procedures and practice may well differ from one Member State to another. The Commission acknowledge that there is no common definition or understanding of hospital care.14 Which Member State’s law/healthcare practice (State of “affiliation” or of “treatment”) will be applicable in order to determine whether the healthcare requires overnight accommodation for the purposes of the authorisation procedure? Yet another problem may arise for the fact that parts of the UK and areas within England may have different priorities and resources available for the delivery of healthcare.

14. The question of classification (hospital/non-hospital) does not exclude the possibility of the patient getting treatment and remuneration but nevertheless there should be clarity (and a good measure of harmonisation, if not uniformity, across the EU) as to when prior authorisation is needed and minimalisation of the opportunities for Member States to erect administrative hurdles for the patient to overcome. The definitions in Articles 4 and 8 therefore require careful consideration and, we suggest, further attention to their drafting.

Procedural guarantees re authorisation of healthcare in another Member State

15. In addition to the requirement in Article 9(1) for objective and non-discriminatory criteria, the effectiveness of the administrative review required by Article 9(5) would be greatly enhanced if there were also an express requirement for reasons to be given in the event of refusal of authorisation of treatment in another Member State, otherwise the “challenge” provided for in Article 9(5) would be worth nothing. Moreover, the experience of Member States’ authorisation procedures suggests that either a deadline for dealing with the requests be imposed or at least that there be a requirement of timeliness.

Member States responsibility for healthcare delivered on their territory

16. It is a regrettable fact that not all treatment is successful or trouble free. The draft Directive indicates that in around 10% of cases “harm” arises.15 Against whom and how easily will the citizen patient have recourse if things go wrong? The clearest answers to these questions are necessary if the proposal is to be a success in providing cross-border access to healthcare.

17. Informed choices as to treatment include information with regard to recourse in the event of defective treatment. The draft Directive is clear as to the responsibility of the State of treatment for remedies.16 However, we believe that the proposal would be improved if it included an express information obligation on

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12 The term used in the Services Directive. See fn 42 above.
13 Explanatory Memorandum para 7.3.
14 Recital 30.
15 Recital 15.
16 Article 5(1)(d)–(e).
Member States for cross-border patients/consumers, informing them at the point of delivery\(^{17}\) of the appropriate avenue for complaints and judicial recourse. The inclusion of such an obligation on Member States would not, we submit, be disproportionate and would seem appropriate in order to ensure that any such recourse satisfies the principle of effectiveness.

18. Further, the draft Directive does not appear to contemplate cases of Member States deciding to transfer (temporarily or permanently) provision of certain standard procedures to other Member States, eg in order to reduce waiting lists at home. This has been a real source of concern in the United Kingdom which has delegated provision of both civilian and military hospital care to other Member States but under entirely different regimes. Thus, in 2002, some routine operations were arranged by UK health authorities in hospitals in Europe and Department of Health November 2002 guidance brought such patients within the standard clinical negligence protocols for treatment in UK hospitals. However, when hospital treatment for the British Rhine army was delegated to German provider hospitals, soldiers and their families were left to pursue all remedies in Germany, with German courts, law and language.\(^{18}\) Such cases raise even greater concerns about the need for informed consent by patients to the risks and implications of being treated outside their place of residence.

November 2008

Memorandum by the Royal College of General Practitioners (RCGP)

1. The Royal College of General Practitioners welcomes the opportunity to contribute to the House of Lords Select Committee on the European Union (Sub-Committee G: Social Policy & Consumer Affairs) inquiry into the European Commission’s proposed directive on the application of patients’ rights in cross-border healthcare.

2. The Royal College of General Practitioners is the largest membership organisation in the United Kingdom solely for GPs. It aims to encourage and maintain the highest standards of general medical practice and to act as the “voice” of GPs on issues concerned with education, training, research, and clinical standards. Founded in 1952, the RCGP has over 34,000 members who are committed to improving patient care, developing their own skills and promoting general practice as a discipline.

3. The College endorses the response of Dr Brian Sweeney, made on behalf of the RCGP Northern Ireland Council. The response, which has already been submitted, is attached here as an appendix.

4. In addition to cross-border healthcare between EU states, the College would also like to highlight the matter of cross-border healthcare between England and Wales and England and Scotland. This is a significant concern to practices who work on the borders.

5. We wish to make the following points on issues relating to cross-border healthcare:

The Role of IT in Supporting Clinician Access to Information

6. IT plays an essential role in allowing clinicians to access information to help patients to be safely treated. There is, however, a tension between providing access to information to healthcare providers and the need to maintain the security of information. This tension is likely to be exacerbated if cross-border provision of healthcare becomes more commonplace. The NHS in England is currently developing Healthspace, a web based portal that enables patients to access and view their clinical information and place information about themselves relating to their health. While the purpose of this new system is to give patients more control over their care, the prospect of such a system operating in a cross-border setting poses an increased threat of data misuse.

Provision of Information to Patients

7. We believe that it is important that patients receive appropriate information about the quality and safety of healthcare providers in other member countries. Service availability monitoring will be required on a live basis, together with the central recording of activity data, and feedback to Member States so that patients are well informed.

\(^{17}\) Articles 10 and 12 do not appear to extend this far.

ENSURING QUALITY AND SAFETY

8. The issues of quality and safety present us with a number of issues to be resolved. Firstly, how will quality be measured in each state and, furthermore, will expectations of quality be the same in each state? An agreement about monitoring the quality of services across states is likely to cause great difficulties. Secondly, how will efficiency and effectiveness be measured, and who will be responsible for making such measurements? Finally, there will need to be agreement on clinical governance issues such as qualifications recognition/experience/training issues, between every one of the Member States.

29 September 2008

APPENDIX

RCGP NORTHERN IRELAND COUNCIL—RESPONSE

PARTICULAR QUESTIONS RAISED BY THE COMMISSION’S DRAFT DIRECTIVE

What do you see as the general advantages and disadvantages of patients having the right to obtain healthcare in Member States other than that where they reside? In what circumstances might patients seek to exercise any such right?

Advantages

1. Access to a health-care service or treatment that is not already available in the Patients’ Member State, or is only available at a distance greater than, a similarly available service, which is based in a neighbouring Member state.

   Example: The current OOH GP services that are currently being piloted here, between Northern Ireland and the Republic of Ireland. Therefore the Patient has the choice to attend another service based outside their state of residence, based upon their preference for a geographically closer and similar service.

2. Access to a health-care service or treatment that is already available in the Patients’ Member State, but the waiting time for which is much longer than that for a similar service, based in another Member state, one to which there is a much smaller waiting time.

   Example: I believe that Patients have been travelling for some time between Northern Ireland and other EU states for operations, such as coronary bypass operations, simply because the waiting time is much shorter.

3. Such movements based upon Patient choice and within such an agreed framework will undoubtedly enhance cooperation in border regions, promote and agree the recognition of prescriptions issued in other countries as well as developing European reference networks, health technology assessment, data collection, quality and safety.

4. Once a framework is agreed then the resident state, the treating state and the Patient will be aware from the outset of the entitlements, the agreed reimbursements, and clinical issues such as follow up.

5. Another advantage of the proposed framework is the assurance of quality, the measurement of such and agreed mechanisms to address complaints and the dealing of significant incidents.

6. Travel within this framework will also promote best practice and deal with the Professional (recognised qualifications/governance requirements) and Indemnity issues from the outset.

7. The wishes, as well as the clinical needs of the Patient are the governing priority and the fulfilment of such, is now possible within the EU context, something that would not have been possible before.

Disadvantages

1. Administrative. This framework I believe, will require a tremendous amount of central administration, in order to set-up, monitor, manage and arbitrate.

2. There will need to be agreement on clinical governance issues such as qualifications recognition/experience/training issues, between every one of the Member States.

3. There will have to be service availability monitoring on a live basis, together the central recording of activity data, and the feedback to Member States so that Patients are well informed.
4. I believe that the issue of clinical follow up, after a procedure is a difficult one, unless clinical responsibilities in both states are established, with named individuals from the outset.

5. How is quality measured/appreciated/expected within each state and are those expectations the same in all states? The agreement, monitoring and assurances of quality across so many systems is bound to cause great difficulties.

6. Will safety be ensured and whose responsibility will it be?

7. How will efficiency and effectiveness be measured and by whom?

What problems do you think have arisen as a result of the present uncertainty in respect of EU citizens’ rights to obtain such cross-border healthcare and to have the costs of this reimbursed by the Member State where they reside?

Problems

1. Equity of access could be seen as a problem, in so far as some individuals settled their entitlements only by bringing their cases to the European Court of Justice. The establishment of this agreed framework is therefore essential in clarifying such positions on entitlement from the outset.

2. It will be important to ensure also from the outset that the provision of services to Patients from other EU States, does not impact negatively upon the normal provision of such services to that Member States own resident population.

3. The issue of follow up is vitally important especially after complicated surgical procedures and so, if this has not been agreed beforehand, the Patient and their GP are then left with the responsibility of trying to find someone willing to take on such a responsibility after a procedure carried out by someone they may very well not know, nor indeed be familiar with the processes involved.

What need do you see for EU level action in this field and, if you do see such a need, what objectives should such action have?

4. There is a need, based upon the activity to date, which though often anecdotal, has been well flagged up the media. If Patients themselves are driving the agenda so far, then I believe that it is imperative that their Member States agree such a framework as soon as possible.

5. Action to address this should be based upon the principles of equity, fairness, efficiency and the assurance of quality, without any detriment to others, within their own states’ healthcare economy and service provision.

What is your view of the extent to which the Commission’s proposed directive will meet the objectives, if any, that you judge action at Community level should have?

1. The Commission is very clear that the proposed framework will not change entitlements, only clarify the process and access to entitlements that are already there.

2. The principles of subsidiarity and proportionality are discussed at length and reiterated many times within the proposal, so the aims right from the start are to ensure that the framework is fair, workable and does not pose any unreasonable threat to any existing services within each Member State.

What conditions, if any, do you feel that Member States should be allowed to impose on citizens’ rights to seek healthcare in another EU country—and to what extent do you think the draft directive satisfactorily makes provision for these conditions?

1. I do think that it is reasonable, to reimburse Patients for such access to healthcare across borders, to a level which would compare to a similar service provided at home. Where such a cost would differ significantly with that at home, I believe that this framework should take that into account on an individual basis, to determine why there is a difference, is it justified and if so, should the Patient or the State bear the cost of the difference.

2. It is also important to establish from the outset, that a State supporting such travel, does not inadvertently undermine its own provision of services and so could be seen as causing any disadvantage to other residents, in essence developing what is referred to as a “two-tier health service”.
What limits, if any, do you think there should be to the level of costs which Member States should be obliged to reimburse to citizens who obtain cross-border healthcare—and to what extent do you think the draft directive satisfactorily makes provision for these conditions?

1. As in the previous question, I believe that reimbursement has to be fair and equitable to that normally expected, however I also believe that the effect of market forces, may result in higher costs, or indeed provision of new and more expensive techniques. In this later case, I personally believe that it would be unfair to ask the Patient to bear this difference, if no reasonable alternative is available.

2. The draft directive does not address these issues in the detail required; however, until a central management/administration system is set up, then I do believe that the magnitude of these difficulties can not be appreciated fully.

What is your view of the likely practical impact of the proposals and of how they would affect day-to-day healthcare provision in the UK? For example, could language difficulties present an obstacle?—Who should be responsible for after care (out-patient and in-patient)?

1. There will be little impact, if all the services required by Patients are available within a reasonable timescale and geography, and in their own States. However, already we are seeing the movement of Patients to access these services outside their own States and the problems of language, clinical governance, funding, quality and follow up are becoming a reality.

2. The framework will not work without the commitment of all those involved (and identified) from the outset.

3. In order to ensure that the framework is working then central administration with overall responsibility, will have to be established together with pathways of redress, where needed and that the opportunities to ensure best practice are shared across all health care systems, involved.

What is your view of the need to limit the medical conditions for which treatment could be sought in this manner?

1. Limiting the conditions and ultimately the cost, should be governed by demand and availability of resources.

2. I imagine that it will be only after a clear analysis has been undertaken of both supply and demand, throughout the EU, will one be in a position to gauge the limit that should apply to services.

How important do you feel it is to ensure that opportunities to benefit from rights to cross-border healthcare are, in practice, made equally available to all citizens and are not confined to just the wealthy or well-educated who may have the knowledge and ability to take advantage of their rights?

1. It is imperative, from the outset that equity of access to such opportunities are ensured and I believe that this can only be undertaken effectively by a central administration/management body, rather than leaving the initiation of such to individual Patients.

How do you think the aim of such equality of access should be achieved and to what extent do you feel that the draft directive is satisfactory in this respect? To what extent, for example, are the provisions on the availability of information sufficiently robust?

1. Information provision is well enshrined within the directive as well as legal entitlement and the guiding principles of subsidiarity and proportionality.

2. However after that, I feel that it would be fairer if Member States brokered such arrangements upon Patients behalf, in general by “block-booking” arrangements, in a coordinated central way rather than leaving the initiative to Patients. States themselves are in a better position to identify shortcomings in terms of access than individuals, and so pro-actively address inequities as they happen, in a coordinated inter-State fashion.

3. At the same time though, where Patients have taken the initiative, themselves, they should be encouraged as well as guided through the process, so that there are no unforeseen detriments.
What are your views on the provisions set out in the draft directive for cooperation between Member States, including: the mutual recognition of prescriptions; the establishment of European reference networks of healthcare providers; e-health; and the management of new health technologies?

1. These are to be welcomed, without doubt.

2. If it is acceptable to receive prescriptions in other Member States, then why are the prescriptions themselves similarly acceptable, as long as issues such as computer generation/language/controlled and other drug regulations are agreed to in advance?

3. There is also no doubt that, the establishment of European reference networks of healthcare providers; e-health; the management of new health technologies are each themselves massive undertakings and again best delivered by a central body who consider all of these issues in a coordinated and common fashion.

Supplementary memorandum by the Royal College of General Practitioners (RCGP)

1. Before answering the specific questions tabled we thought it would be pertinent to raise the issues which we believe will most significantly affect GPs.

GP Role within Cross-border Directive

2. The issue of information has been raised consistently in this debate and we would argue that the need for healthcare professionals themselves to be in receipt of quality information is absolutely critical.

3. GPs cannot refer patients without complete and clear information regarding the care they can expect their patient to receive. The GMC demands that GPs refer only to those healthcare professionals who they are satisfied are competent to carry out the treatment. GPs must be able to assure themselves of the quality and standards of care and the good regulatory standing of the providers in other countries. This cannot be stressed enough.

4. The role of the GP to advise patients on referrals and possible courses of action cannot be undermined. When a patient decides to seek cross border treatment the burden placed upon the GP should not be more than that of a regular domestic referral.

5. The administrative burden will be substantial. We would welcome some form of central administration, in order to set-up, monitor, manage and arbitrate the functioning of the framework.

6. We would welcome the identification of national contact points. A person whom patients could contact to receive up-to-date, clear and totally comprehensive information which would help them to decide whether to travel to access health care across borders. The burden should not be placed upon GPs to supply this information as it would be more efficient if patients could access this information direct and there is at present no reliable mechanism for keeping GPs updated on all relevant information. The role of information provider for Cross border health care would be an unwelcome addition to most GPs workload.

Gatekeeper Function of GPs

7. The gatekeeper function of GPs is essential to the efficient running of the NHS and is both defended and sought by GPs in other Member States. It is key to the safety and cost effectiveness of health care and should not be undermined by any arrangements to access health care across borders.

8. Once the patient has decided to pursue a referral it is at that point when an information contact point could supply the required information so that the patient can make an informed choice.

9. It must be clear how this system will operate in member states where there is a shortage of GPs acting in a gate-keeping role and not such a developed network of primary care physicians.

Issues Affecting Border-lying Practices

10. Due to the increased relevance of this draft Directive to those patients who live near to border regions, as already witnessed between Northern Ireland and the Republic of Ireland, practices in those areas must be fully prepared for the introduction of the Directive because of the volume cross border flows.
Q1. What are your views on the equity of the proposed directive? How well do you think the proposal addresses issues of equity, including the requirement for a patient to pay upfront for their cross-border treatment?

11. The framework should be based upon the principles of equity, fairness, efficiency and the assurance of quality, without any detriment to patients in their own states’ healthcare service.

12. It is imperative that the procedures detailed in the Directive do not discriminate against any patient and that all are able to use the Directive regardless of income.

13. The proposals do not make it clear what the arrangements for reimbursement of travel expenses by the Member State should be. Clarification is needed.

14. If aftercare is to be the responsibility of the providing state, the continued expense of travel and accommodation could be prohibitive, even for the wealthiest of patients. This raises more questions regarding the requirement to pay upfront for treatment.

15. A central administration/management body would be the most effective method of ensuring equity of access to these opportunities.

16. There may also be an inequitable impact on the care of patients electing to remain in their own Member State for care. Available budgets for home based care might be reduced by the need to reimburse those electing to travel. Those travelling may be doing so in order to reduce their waiting time if, due to clinical prioritisation, they have been placed farther down the list. This may then impact upon those higher up on the list if the need to pay for cross-border treatment adversely affects the waiting time for all. Again a central administration/management body may neutralise this possible outcome.

Q2. What do you think of the potential for patients to ‘top up’ that is created by the proposed directive? How do you think this should be addressed, particularly with regard to the principle of equity?

17. This directive does carry with it the potential for patients to “top-up” their healthcare.

18. Inequity occurs at two levels: firstly between patients in the UK; ones who can afford to top-up their NHS treatment by seeking to go abroad or pay for non-NHS funded drug treatment in the UK. Secondly it could occur between UK patients and EU patients where a drug is not available in the UK but is in another EU area.

19. The issues relating to cross-border top-up and domestic top-up are similar. It is inevitable that a degree of inequity will occur but the ruling of Professor Mike Richards has set a precedent, allowing patients to top-up as long as they pay for all costs relating to that episode of care. How top-ups will operate within this cross-border directive needs clarification.

Q3. In your written evidence you all identify the importance of providing information to patients. Whose responsibility do you consider it should be to provide this information and what do you think such information should consist of? What is your view on the need to consider and address the information requirements of health professionals in addition to patients?

20. The issue of information is vitally important to patient safety and patient confidence. It is essential that patient’s receive accurate and appropriate information regarding the quality and safety of healthcare providers in other Member States.

Information for patients should include: quality, the nature and costs of the treatment, what the corresponding treatment would be in the home state for the same condition, service availability (kept up-to-date on a live basis) and information regarding the cultural aspects of healthcare in the providing country so the patient knows exactly what they can expect.

21. The provision of language support such as an interpreter service will be essential when appropriate.

22. As the provision of information is so vital to the functioning of this system the administrative burden upon clinicians could be substantial. Therefore, as mentioned above, we welcome the proposal for national contact points who will not only alleviate this burden but will hopefully also provide expert advice and therefore instill confidence in the user. The information should be provided by the provider with additional information, as is deemed to be relevant by the central administration of the Home State, based on expected differences between care available at home and abroad. We would also stress that service users should be involved in quality assurance of this information.

23. There is a tension between providing access to information to healthcare providers and the need to maintain the security of information. This tension is likely to be exacerbated if cross-border provision of healthcare becomes more commonplace.
24. We would like to draw the Committee’s attention to the Healthspace programme and the potential implications that cross-border treatment would have on this system. Healthspace is currently only available to English patients, it contains various pieces of information, including their summary of care and other information which, the patient themselves, can choose to input if they wish. The NHS cannot share this information with physicians in other countries, however if the patient chooses they can access their Healthspace account via the internet and share it with a doctor.

Q4. Could you explain to us your experience with existing methods of cooperation? What is your view on the draft directive’s provisions for cooperation between Member States, including European reference networks? What do you consider to be the potential advantages and/or drawbacks of such provisions and what other measures (if any) do you think should be introduced?

25. In our written evidence we made it clear our approval of increased cooperation across state borders.

26. A subsequent issue is that of prescription recognition. We welcome this, however issues around language and drug regulation will have to be resolved first. Again clear information for dispensing GPs and pharmacists regarding drugs prescribed abroad but not approved here will be needed.

Q5. What is your view of the proposed system of prior authorisation? In particular, do you think the respective definitions of ‘hospital care’ and ‘non-hospital care’ are made clear in the proposed directive, and reflect different practices across the European Union? What is your view of the exclusion of non-hospital care from the system of prior authorisation and do you consider that a case can be made for all patients seeking care abroad to be subject to prior authorisation procedures?

27. In our opening comments here we addressed the issues surrounding prior-authorisation and the GP gatekeeper role.

Q6. As representatives of healthcare service providers, to what extent do you liaise with your counterparts in other EU Member States, for example, do you have a collective European body representing service providers from across the EU? Are you aware of their views on the proposed directive, and if so, how do these views compare to your own?

28. The RCGP is a member of Wonca Europe (World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians, or World Organization of Family Doctors for short and we have representatives to the Wonca European Network Organisations (EURACT, EGPRN, EQUIP and VdGM).

29. Wonca Europe has 40 member organisations (representing more than 45,000 family physicians in Europe) and is the academic and scientific society for GPs in Europe.

30. The RCGP also has a representative at both the European Forum of Primary Care and UEMO (European Union of General Practitioners). Not all members of the EU are members of the UEMO.

31. In general UEMO and its members are supportive of the proposals as a vehicle to promote high quality healthcare for all across Europe and to maintain and promote the gate-keeping role of GPs.

Concerns include:

(a) quality assurance issues across borders where funding frameworks and investment levels differ; and

(b) continuity and security of health and patient related information between health care professionals in different Member States.

32. We note that the European Forum at the BMA did not accept that the number of patients utilising the directive would be small. The Northern Ireland/Republic of Ireland cross-border flows are already significant in some specialties, and the effect on small Member States seems not to have been realistically calculated by the Commission.

33. The European Forum was of the view that the effect on the home systems budgets and capacity could be disproportionately large.
Q7. What are the main issues of devolution that need to be addressed in order to ensure the successful implementation of this directive in the UK? How do you think these issues should be addressed?

34. See our remarks above and in our original submission concerning practices who live close to borders and landlocked countries.

Q8. How can the quality of healthcare, safety for patients, and appropriate aftercare most effectively be assured, particularly in light of the complex pathways of care that may arise as a result of the cross-border dimension? What lessons can be learnt in this regard from the London Patient Choice project, covering patients who were sent to five hospitals in Belgium during the period 2003–04?

35. The standardisation of quality brings to light some stark problems. Can firm agreements on frameworks and standards for monitoring the quality of services acceptable to all Member States be put in place? How will quality be measured in each Member State? Will the expectations of quality be the same between different states?

15 January 2009