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European Union Committee

4th Report of Session 2008–09

Healthcare across EU borders: a safe framework

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(Q) refers to a question in the oral evidence

(p) refers to a page of written evidence

The Report of the Committee is published in Volume I (HL Paper 30–I) and the Evidence is published in Volume II (HL Paper 30–II)

Summary

The right of patients from EU Member States to travel to another Member State to receive healthcare is a principle that has been confirmed on a number of occasions over the last ten years by the European Court of Justice, but uncertainty remains over how that right should function in practice. In an attempt to provide some clarity, the Commission published its proposal for a Directive on the application of patients' rights in cross-border healthcare.

Our report examines the proposal and considers that it is a justified and necessary attempt to codify ten years of European Court of Justice case law. Until now, patients' rights in cross-border healthcare have evolved through courts rather than considered legislation, and we do not consider that to be sustainable.

The Council of Ministers recognised the need for a legal framework in 2006, and the European Parliament has been similarly supportive. In our report we have emphasised the need for a proportionate response that does not go beyond what is necessary to provide clarity over patients' rights and fully respects the constitutional arrangements of each Member State, such as the UK's system of devolved governance.

The right to access cross-border healthcare presents patients with choice, an opportunity which we welcome, particularly if it has a positive effect on the efficient delivery of health services locally. Along with choice, we have recognised too that equity must underpin the drafting and implementation of this legislation. This means equitable access to cross-border healthcare for all, regardless of financial means, but avoiding any distortion of national health services. We are confident that Member States' right to organise and deliver their own health services and medical care may be protected under this draft Directive.

The demand for cross-border healthcare is, at best, unclear and it is likely to differ significantly across the European Union with demand greater in countries that share land borders or, for reasons of size, lack certain specialities. The precise mechanisms required to deliver it are equally unclear. Our report identifies some of the challenges to be met that are unresolved in the Directive as drafted, such as: delivering a smooth pathway of care for patients; ensuring that patients and practitioners are able to communicate with one another; and collating and disseminating information on cross-border healthcare.

We understand and accept the need for the legislation but we consider the impact to be so hard to predict, and potentially very significant for patients and practitioners alike, that the implementation of the Directive must be submitted to early, rigorous and regular review.

Healthcare across EU borders: a safe framework

CHAPTER 1: INTRODUCTION

Cross-border healthcare: Background to the Commission's initiative

1. On 28 April 1998, the European Court of Justice (ECJ) ruled that EU citizens have a right to obtain planned medical and dental treatment in a Member State other than their home State (see Box 1). Just over ten years later, the European Commission published a proposal for a directive on cross-border healthcare,¹ which aims to clarify and facilitate these rights in relation to cross-border healthcare and to provide some legal certainty. That proposal is the subject of this report.
2. The Commission's proposal and our report are not about the right to unplanned emergency treatment abroad, which is covered by the European Health Insurance Card.² This allows all EU citizens to use the same state-provided healthcare as residents of the country that is being visited. Nor are the proposal and our report about the mobility of healthcare professionals, which is covered by Directive 2005/36/EC on the recognition of professional qualifications.³

BOX 1

The key provisions considered by the ECJ

Article 49: The free movement of services

Article 49 of the EC Treaty provides that restrictions on the freedom to provide services across borders within the Community shall be prohibited. This prohibition also applies to restrictions on the receipt of services. Healthcare is a service covered by this Article.

E112: The cross-border application of social security schemes

Article 22 of Regulation 1408/71 of the Council of 14 June 1971 on the cross-border application of social security schemes⁴ allows nationals of EU Member States to travel to other Member States for treatment, at the cost of the relevant authority in the home Member State, as long as they have been authorised to do so by that authority. Authorisation may not be refused where the treatment is among the benefits normally provided within the home Member State and where the treatment cannot be provided within the normal time necessary, taking into account the current state of health and probable course of treatment. This is otherwise known as the “undue delay” clause. “E112” refers to the number of the necessary administrative form.

Article 152(5): Competence over national health services

Article 152 of the EC Treaty gives the Community a limited right to act in the field of public health but, according to Article 152(5), Community action should fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.

¹ Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare (COM(2008)414), 02.07.2008

² www.nhs.uk/EHIC/Pages/About.aspx

³ Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ L255, 30.9.2005, pp 22–142)

⁴ Council Regulation (EEC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community (OJ L 149, 5.7.1971, pp 2–50)

3. The two 1998 cases⁵ both related to Luxembourg citizens who had been denied reimbursement for non-hospital medical services provided abroad. In the *Kohll* case, Mr Kohll's social security institution refused authorisation for his daughter to travel to Germany for dental treatment. The ECJ decided that rules under which reimbursement of the cost of dental treatment provided in another Member State is subject to authorisation constitute a restriction to the freedom to provide services. In the *Decker* case, Mr Decker was refused reimbursement for spectacles that he had bought across the border in Belgium using a prescription issued in Luxembourg. In that instance, the ECJ decided similarly that the rule constituted a restriction to the free movement of goods. It recognised that such a restriction could in principle be justified if it were necessary to ensure the financial balance of the social security scheme, maintaining a balanced medical and hospital service to all of its insured persons. But in these cases that justification was not established.
4. Since 1998, the ECJ has delivered further judgments clarifying its reasoning. One such judgment was the *Watts* case, delivered on 16 May 2006.⁶ In 2002, a UK citizen, Mrs Watts, investigated the possibility of hip arthritis treatment abroad on the basis of an E112 form (see Box 1). The request was refused because the projected one-year wait for the operation was within Government targets and therefore could be considered to be "without undue delay" (one of the criteria for an E112 authorisation). Upon appeal, Mrs Watts' case was reviewed and considered to be more urgent, but it was felt that the revised period of three to four months was still "without undue delay". Having failed to secure prior authorisation, Mrs Watts proceeded with treatment in France and continued her case against the local Primary Care Trust.
5. Ruling on the *Watts* case, the ECJ considered the application of both the "E112 route" and Article 49 (see Box 1), and of their interaction with Article 152(5) of the EC Treaty. The ECJ emphasised that consideration of undue delay must extend beyond the existence of waiting lists and overall clinical priorities, and must consider the specific clinical needs of the individual patient. It judged that Mrs Watts had faced "undue delay" and that failure to grant prior authorisation contravened both Regulation 1408/71 and Article 49, EC.
6. The Court also considered reimbursement under the E112 scheme and Article 49. Where an E112 form is used the treatment costs would normally be paid by the social security institution of the host Member State as they would be for one of its nationals, with the social security institution of the home Member State reimbursing the authority of the host Member State direct. Where a national of the host Member State would be required to make a contribution to the cost of the treatment, as is the case in some EU Member States, the home Member State must reimburse any such contribution by a patient from the home Member State, subject to the following condition: the total amount to be paid by the home Member State should not exceed the cost of equivalent treatment in the home Member State or (if lower) the amount invoiced for the treatment by the host Member State. Where Article 49 alone is relied upon the reimbursement to the patient

⁵ Case C-158/96 *Kohll vs Union des Caisses des Maladies* [1998] ECR I-01931 and Case C-120/95 *Decker vs Caisse de maladie des employés privés* [1998] ECR I-01831.

⁶ Case C-372/04 *Watts vs Bedford Primary Care Trust* [2006] ECR I-4352.

of the cost of the treatment can be limited to the cost of equivalent treatment in the home Member State. In either case ancillary travel and accommodation costs incurred by the patient must be reimbursed by the home Member State if its own national system provides for these costs to be met.

7. In June 2006, EU Health Ministers agreed a Statement on common values and principles in EU health systems⁷ (see Box 2). This political discussion reflected the need to clarify how the health services provided by national health systems should apply the Treaty provisions on the free movement of services. Ministers explicitly called for a legal framework enshrining these values and principles in order to ensure legal certainty, while also respecting the restricted Community competence in relation to health policy. Article 152 of the EC Treaty gives the EU competence to act in the field of public health, but Community action should fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. The question of competence is explained and examined in Chapter 3 of our report.

BOX 2

Values and principles of EU health systems

At their June 2006 meeting, the Council of Health Ministers agreed the following set of overarching values that underlie the delivery of health services throughout the EU:

- Universality (that is, no-one is barred from access to healthcare);
- Access to good quality care;
- Equity (equal access for all regardless of ethnicity, gender, age, social status or ability to pay);
- Solidarity (makes the link between the financing of national health services and accessibility to all).

Ministers noted that different Member States have different approaches to making a practical reality of these values and emphasised that, whilst it is not appropriate to standardise health systems at an EU level, there is immense value in work at a European level on health care that enables the sharing of experiences and information about approaches and good practice.

Ministers agreed the following set of operating principles:

- Quality;
- Safety;
- Care that is based on evidence and ethics;
- Patient involvement;
- Redress;
- Privacy and confidentiality.

⁷ Council of the European Union, 9658/06

8. On 26 September 2006, the Commission published a consultation paper regarding Community action on health services,⁸ laying out the need for action and the possible areas of Community action. We considered the issues raised to be difficult and sensitive and therefore held an oral evidence session with the UK Health Minister, Rosie Winterton MP, on 25 January 2007. The transcript of that session was published as a report on 28 February 2007.⁹ In that short report, we indicated that we would look further at these issues upon publication of a legislative proposal by the Commission.

The Commission's proposal

9. The Commission's proposal is summarised in Box 3. Its elements will be explained in further detail in the respective chapters of this report. In justifying its proposal, the Commission refers extensively to the ECJ jurisprudence¹⁰ and to the June 2006 Council Conclusions (see Box 2). Furthermore, it offers some details on the practical nature of cross-border healthcare. While comprehensive data are not yet available, the Commission estimates in its impact assessment that cross-border healthcare is responsible for around 1% of public expenditure on healthcare.¹¹ The Commission explains that patients prefer healthcare to be delivered close to home but there are situations when cross-border healthcare can be more appropriate. These include highly specialised care, treatment in border regions and lack of local capacity. Another reason is that those who have moved from one EU country to another in order to work may wish to return to their home country for healthcare, as is demonstrated in the UK by the high number of E112 cases involving maternity care (see pp 31–34). Finally, cheaper healthcare may be an attraction for those patients who may be paying a high proportion, or all, of the costs of their healthcare.
10. Summarising the issues to be addressed by the proposal, the Commission explains that it is necessary, first, to address how the free movement rights recognised by the ECJ for citizens to have access to healthcare abroad can be applied in practice. The second key issue is to work out how to ensure that, when cross-border healthcare is provided, it is safe and efficient.

BOX 3

Summary of the Commission's proposal¹²

Scope: The directive will apply to all healthcare, regardless of how it is organised, delivered and financed or whether it is public or private. Healthcare itself is not defined in the Directive.

Responsibilities of host Member States: Host Member States are required to ensure that clearly defined quality and safety standards are applied, that healthcare providers make all relevant information available to patients in order that they can make an informed choice, that redress mechanisms are in place, that systems of professional liability apply, that the right to the protection of personal data is respected and that equal treatment between nationals of different Member States is assured.

⁸ SEC(2006) 1195/4, 26.09.2006

⁹ Cross Border Health Services in the European Union, European Union Committee, 8th Report (2006–07) (HL 48)

¹⁰ As outlined above and including also Case C-368/98 *Vanbraekel* [2001] ECR I-5363; Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473; Case C-56/01 *Inizan* [2003] ECR I-12403; Case C-8/02 *Leichtle* [2004] ECR I-2641; Case C-385/99 *Müller-Fauré and Van Riet* [2003] ECR I-4503.

¹¹ SEC (2008) 2163, 02.07.2008 (p9)

¹² (COM(2008)414)

Use of healthcare in another Member State: Home Member States should ensure that a patient is able to access treatment in another EU Member State on the same basis as that patient would be able to access care at home. Prior authorisation should not be applied to non-hospital care but can be applied to hospital care as long as it is justified and does not constitute a means of arbitrary discrimination.

Information provision: Home Member States must ensure that information on receiving healthcare in another Member State is easily accessible and available to patients on request. As part of that process, National Contact Points must be established in each Member State to provide and disseminate information to patients on their rights.

Member State co-operation: A number of tools are included to enhance co-operation, including the cross-border recognition of prescriptions, the development of European reference networks of healthcare providers, the interoperability of information and communication technology systems, co-operation on management of new health technologies, and data collection.

11. The Commission's proposal is the subject of discussions in Brussels among Member States in the Council of Ministers and in the European Parliament's Environment, Public Health and Food Safety Committee, which is expected to adopt an initial position in March. The co-decision procedure applies so, if the proposal is to become law, both the Council of Ministers (representing the Member States acting by a qualified majority) and the European Parliament will have to reach an agreement. At the time of writing, a likely timetable for agreement was not known.

Our inquiry

12. Our inquiry had a number of aims. First, we sought to assess the extent to which the draft Directive provides the necessary legal clarification. Second, we examined whether the proposal respects the values and principles adopted by Health Ministers in June 2006. Third, we assessed the extent to which the Commission's proposals are practical, and whether they are likely to provide patients with sufficient guarantees on safety, continuity of care and redress mechanisms. Finally, we sought to examine whether the complexity of the measure is proportionate to the scale of the issue.
13. The Members of our Social Policy and Consumer Affairs Sub-Committee (Sub-Committee G) who conducted the inquiry are listed in Appendix 1, showing their declared interests.
14. We are most grateful for the written and oral evidence that we received for our inquiry; the witnesses who provided it are listed in Appendix 2. In particular, we thank those witnesses who gave evidence in person. The Call for Evidence we issued is shown in Appendix 3, and the evidence we received in response is printed in a companion volume to this report.
15. **We make this report to the House for debate.**

CHAPTER 2: OVERALL OBJECTIVE AND THE NEED FOR ACTION

The issue

16. In this chapter we discuss the need for action in the field of cross-border healthcare within the European Union and consider what the objectives of this action should be and which areas will require particular attention to ensure that they are not adversely affected by the new legislation. We also discuss review of the Directive after its implementation.

Contents of the proposal

17. The proposal's aim is set out in Article 1, which provides that "This Directive establishes a general framework for the provision of safe, high quality and efficient cross-border healthcare."¹³
18. The Commission's Explanatory Memorandum identified a need to increase the clarity of the ECJ rulings on cross-border healthcare, in order to ensure a more general and effective application of freedoms to receive and provide health services (as discussed in Chapter 1).¹⁴
19. Based on this case law, the Directive aims to ensure a clear and transparent framework for the provision of cross-border healthcare within the EU. The objectives of this framework will be to provide sufficient clarity about patients' rights to be reimbursed for healthcare provided in other Member States and to ensure that the necessary requirements for high-quality, safe and efficient treatment are ensured for cross-border care.¹⁵
20. The Directive provides that within five years of its transposition, the Commission shall submit a report on the operation of the Directive to the European Parliament and the Council. To assist with the preparation of the report, Member States are required to communicate any measure they have introduced, modified or maintained with a view to implement the procedures laid down in Articles 8 and 9 (on prior authorisation).¹⁶

Need for action

21. Much of the evidence we received supported the Commission's view that there was a need for increased clarity on cross-border healthcare, particularly in view of the ten-year history of ECJ case law in this area (as discussed in Chapter 1). (QQ 2, 48, 140, 189, 236, pp 16–17, 54, 60, 61, 75, 88, 91, 115, 159, 166)
22. The Government suggested that the case law had created uncertainty in several areas, including over reimbursement levels, responsibility for determining entitlements from state systems, the rules for refusing prior authorisation and the principles of clear and transparent costing systems. (p 16) However, the supplementary evidence from Dawn Primarolo MP, Minister of State at the Department of Health, made clear that current levels of cross-border movement for healthcare are relatively low: 552 E112 forms

¹³ (COM (2008) 414) Article 1

¹⁴ (COM (2008) 414) (p2)

¹⁵ (COM (2008) 414) (p4)

¹⁶ (COM (2008) 414) Article 20

were issued to UK Citizens for treatment abroad in 2007. (pp 31–33) In addition, the Government's Impact Assessment indicated that an estimated 50,000 people per year currently travel from the UK to other European countries for "health reasons".¹⁷ No figures on the inflow of patients travelling to the UK from other EU countries to receive medical treatment could be obtained during our Inquiry.

23. The British Dental Association stated that "Case law ... 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 ... it is important that their rights and responsibilities are clear ... and that they are appropriately protected." (p 115)
24. The need for clarity about the patient's own responsibility was also highlighted by the Minister: "We need the clarity that this is not a referral ... They [the patient] are making an individual choice and they take the responsibility for stepping outside the NHS." (QQ 77–78) This point was also made by the NHS Confederation who emphasised the additional degree of personal responsibility that patients would take on when choosing to access cross-border healthcare. (p 105)
25. The Royal College of Nursing (RCN) recognised that the lack of clarity resulting from the ECJ case law impacts upon professionals as well as patients, and the Patient Liaison Group of the Royal College of Surgeons highlighted the need to ensure fairness between the Member States through action at EU-level, so that none of them would become overwhelmed by cross-border patients. This is particularly important in light of the fact that no comprehensive data on cross-border healthcare are currently available, making it difficult to predict what the levels of cross-border movement will be (see paragraph 9). (pp 54, 91)
26. Some witnesses laid emphasis on wider objectives than just legal certainty. The Law Society supported a particular benefit of the new legislation: to remove the barriers patients are faced with in seeking cross-border healthcare. (p 166) In relation to this objective, the Association of British Insurers stressed that "There is a distinction between removing barriers to accessing healthcare and facilitating access to the extent that it undermines individual Member States' healthcare systems" and the RCN highlighted the need to ensure that domestic provision and financing are not undermined by the Directive. (pp 91, 159, Q 242)
27. Much of the evidence we received suggested that the proposal should also include the safe availability of healthcare across borders within its aims, taking particular account of patient safety and redress. (pp 72, 75, 117, 166) The British Medical Association in particular were of the view that patient safety and the provision of high-quality clinical care should be the overriding priorities of any new legislation and were supported in this view by the General Medical Council and the Nursing and Midwifery Council who both stressed the importance of strengthening regulation across the EU to improve patient safety. (p 117, QQ 234, 236)

¹⁷ www.dh.gov.uk/en/Consultations/Liveconsultations/DH_089029

Need for caution

28. Despite widespread consensus about the need to clarify the case law on cross-border healthcare, witnesses expressed concern about the overall scope of the Directive. The Minister cautioned that “The principle is to codify the case law that we have now and not to open up any other areas ... 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.” (Q 48) The NHS Confederation supported this point: “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”. (p 88)
29. Unite believed that the Directive went beyond patients’ rights and both highlighted an area which they felt should be excluded from the overall objective for EU-level action in cross-border healthcare: the creation of an EU single market in healthcare services. (p 135) UNISON considered that “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”. Unite agreed, fearing that the Directive as it currently stands constitutes an attempt to create a single market in healthcare. (pp 132, 135)
30. The RCN was concerned about the tension between the objectives of the single European market for the free movement of individuals and services (the treaty base for this proposal) and the need for national health systems to plan a whole service within limited budgets and to ensure equity. (Q 242)
31. Proportionality¹⁸ was also recognised as an issue in relation to any action used to achieve the main objectives of the proposal. The NHS Confederation stressed that in view of the small numbers of patients availing themselves of cross-border healthcare (see paragraph 22), the systems introduced to address this should not be disproportionate in scale or costs. This was recognised by the British Medical Association as a problem between balancing patients’ rights and patient-centred treatments with the fundamental NHS principles, including equity, which was one of the principles laid down by EU Health Ministers in 2006 (see Box 2). PA Consulting questioned whether, in this context, the benefit to the small number of patients was worth the potential disruption to Member States’ health systems and the additional costs that would be incurred. (pp 2, 88, Q 286)

Forecasting levels of demand

32. Conversely, PA Consulting suggested that the increased patient choice created by the Directive would alter hospitals’ incentives. If patients could move away from their local hospital (for example if there were long waiting lists or they did not perceive the care to be of high quality), that would create a strong incentive for the hospital to address those problems, especially in systems where funds went with the patient. PA Consulting suggested that orthopaedic departments in the UK—some of which have long waiting lists—might see more patients going abroad to receive treatment. They also pointed

¹⁸ This is not a reference to the principle of proportionality as defined in Article 5 of the Treaty establishing the European Community: “Any action by the Community shall not go beyond what is necessary to achieve the objectives of this Treaty”.

out that these effects would not necessarily be permanent and could be self-correcting, since the relevant hospital or department would then work to reduce its waiting lists, in which case patients would no longer travel to other healthcare facilities for treatment. (Q 4)

33. The Minister reported that it is difficult to foresee what the inflow of patients into the UK may be under the Directive and that there are questions around how this would be sustainable and reasonable. (Q 58) The Patient Liaison Group of the Royal College of Surgeons (PLG) considered that it would not be sufficient to assume that current levels of patient demand will be the norm once the Directive comes into force. (Q 143) They highlighted the importance of these flows to healthcare delivery, suggesting that heavy demand for treatment in some countries could be disadvantageous to local populations. (p 53) Travel across the border between Northern Ireland and the Republic was used as an example by the British Medical Association who stated “it is going to be crucial there to work out what those numbers will be to make sure that the healthcare services on both sides of the border are not destabilised.” (Q 287)
34. The PLG stressed that “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.” (Q 155) One way in which the issues may be teased out is through the Commission’s proposed review of the Directive within five years of adoption. The EU Health Commissioner, Androulla Vassiliou, stressed that collection of comparable data would be very important for the successful review of the Directive. She believed that five years was a reasonable time to allow for the Directive to be fully developed in order that reliable data could be obtained. However, she assured us that if the Member States felt a review should happen earlier, the Commission would not object. (Q 400)

Conclusions and recommendations

35. Ten years of case law on cross-border healthcare have not provided the clarity needed by both patients and healthcare providers. We therefore agree that **the main rationale for the Directive should be to clarify the application of treaty provisions to health services.**
36. Whilst we recognise the need for action on these grounds, **the response must strike a proportionate balance between individual choice on the one hand and effective delivery of public health provision, within limited budgets and reflecting different national and sub-national practices, on the other.** Failure to strike a balance between these two objectives could be detrimental for all patients.
37. **We take the view that the fundamental objective of the proposal should be to ensure that a framework is in place to deliver the availability of healthcare across borders but without excessive complexity and without harming the delivery of national health systems at a local level, and taking particular account of patient safety and redress.**
38. We recall the set of overarching values underlying the delivery of health services throughout the EU that were agreed by EU Health Ministers in 2006 (see Box 2). This also finds expression in recitals 11 and 12 of the Directive. We consider above all that **Member States must ensure that the principle of equity, within the terms of Member States’ own**

health systems, underpins the negotiation and implementation of the Directive.

39. We note the argument that the introduction of patient choice may force hospitals to become much more responsive to patient needs and acknowledge that this may provoke adjustments to the services offered by Member States through the mechanisms and the incentives that choice creates. **Choice is welcome if it has a positive effect on the efficient delivery of health services locally. In particular, we recognise that the proposal could have a positive effect where there are particular specialities with very long waiting lists. However, we recommend that effective delivery at the local level must remain a key objective.**
40. It is clear that it will not be possible to identify the Directive's impact until it has been transposed. **We therefore conclude that the Directive should be reviewed within three rather than five years after it comes into effect**, in order that Member States can learn lessons from the experiences of cross-border healthcare sooner rather than later.
41. Given the importance of patient inflows and outflows to the stable and secure delivery of healthcare in Member States, **we believe that the report produced by the Commission should include information on patient inflows and outflows.**

CHAPTER 3: LEGAL AND REGULATORY CONSIDERATIONS

The issue

42. In this chapter we examine whether the Commission's proposed legal base for the proposal is appropriate, and whether the proposal respects the relative competences of the Member States and the Community in the field of healthcare. We also examine whether the proposed Directive is sufficiently clear in setting out how it relates to other relevant legislation.

Legal Base

43. Every piece of EU legislation must have a legal base in one of the EU Treaties.¹⁹ This sets out the power for the Institutions to act and the procedure for doing so. The Commission has based this draft Directive on Article 95, TEC, under which the Community is able to adopt harmonising measures to facilitate the establishment and functioning of the internal market. Article 95(3), TEC further stipulates that any Article 95 proposal relating to health must ensure a high level of human health protection. A measure can be properly adopted under Article 95 if it would genuinely assist in overcoming the restrictions on the provision of healthcare services.
44. Although not its legal base, the proposed Directive also refers to Article 152, TEC which provides for limited Community action in the area of public health. It states specifically that a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities (which include the internal market). Article 152(5) specifies 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." Any measures that harmonise the laws and regulations of the Member States are excluded from Article 152, which means that the proposed Directive could not rely on that Article as a legal base.
45. When deciding on the appropriate legal base, it is necessary to compare the aim and content of the proposal against the powers conferred by the particular legal base (see paragraph 43 above). The Commission indicates in the Explanatory Memorandum to its proposal that the aim of the proposal is to "establish a general framework for provision of the 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, whilst fully respecting the responsibilities of the Member States for the organisation and delivery of health services and medical care".²⁰ The Commissioner explained to us that, as the ECJ had determined that Article 49 prohibits restrictions to the free movement of health services, it was necessary to adopt the legislation under the internal market legal base (Article 95), but she also emphasised that Article 152 is at the centre of the Directive, thus respecting the competence of the Member States in healthcare. (Q 379) The Minister considered that Article 95 was "the correct legal base for negotiation" while

¹⁹ Either the Treaty on European Union (TEU) or the Treaty establishing the European Community (TEC), depending on the issue.

²⁰ (COM (2008) 414) (p6)

acknowledging that a legal base can sometimes shift in the course of negotiations. (Q 52)

46. The choice of Article 95 as a legal base was, however, questioned by the Law Society for England and Wales. Their concern related to the question of whether the full content (rather than the objective) of the proposal is in line with Article 95. They acknowledged that health policy is not excluded from being the subject of measures adopted under Article 95 but “the existence, extent and limitations of Article 152 are, we believe, significant.” (p 166) In particular, they questioned whether Article 95 could legitimately be used as a legal base for laying down the responsibilities of Member States (Article 5 of the draft Directive) and for the co-operation mechanisms relating to e-health, European reference networks and the management of new health technologies (see Chapter 8).
47. We understand that similar concerns have been raised in the Council of Ministers, particularly as regards the extent to which paragraphs one and three of the draft Directive’s Article 5 are in accordance with Article 152(5) of the Treaty. Paragraph one of Article 5 lays down the responsibilities of the host Member State and paragraph three allows the Commission to develop guidelines to assist Member States in meeting those responsibilities.

Right of host State to refuse

48. An argument that was advanced by a number of witnesses in defence of the proposed legal base was that, under the draft Directive (recital 12), Member States would not be required to accept for planned treatment, or to prioritise, patients from other Member States to the detriment of other patients with similar health needs. The Minister agreed that Member States’ ability to take their own decisions on capacity was important, stating that “our first duty is to the overwhelming majority and that is how we plan and manage the Health Service nationally.” (Q 60) PA Consulting supported this clause in the Directive but indicated that clarification was required on what was meant by “detriment”. (Q 11)
49. The Commissioner assured us that Member States will have this right of refusal as long as it is applied in a non-discriminatory fashion, based on a Member States’ capacity to provide care. (Q 380)

Delegating legislative power to the Commission

50. EU legislation frequently gives the Commission power to make subordinate regulations or take other action, overseen by committees made up of representatives of the Member States, and this Directive does so. This procedure is known as “comitology”, and is governed by Community rules.²¹ Under the proposal, the Commission would have the power to take decisions on a range of details, including the definition of “hospital care” for the purposes of prior authorisation (see Chapter 4). That power is subject to the Regulatory procedure, which is one of the more stringent procedures available. Under this procedure, the Commission proposal needs the approval of a qualified majority of the committee in order to be adopted by the Commission. If the proposal does not secure such approval, it is referred

²¹ Council Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission.

to the Council for a decision. The proposal can then be adopted if the Council either agrees it by a qualified majority or fails to secure a qualified majority against it.

51. Among our witnesses, one notable source of concern in discussion of the legal base and the possibility that the rights of Member States as provided under Article 152(5) might be infringed was the widespread reliance in the draft Directive on the delegation of decisions using this comitology procedure. The Minister questioned why it was necessary to delegate these decisions to such committees if the primary aim of the Directive was to codify ECJ case law. She warned that “there is always the danger that either inadvertently or by design it goes further than we intended”. (Q 52) UNISON considered that these provisions would give powers to the Commission that were never intended. (Q 334) The General Medical Council asserted that the role of the implementing committees should be defined and limited in order to avoid future “disproportionate, unanticipated and inappropriate spill-over into the national regulatory role.” (p 74)

Subsidiarity

52. Article 5, TEC, states that “the Community shall take action ... only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community” and that this “shall not go beyond what is necessary to achieve the objectives of this Treaty.”
53. The Commission argues in its impact assessment²² that Community level legislation on cross-border healthcare is necessary for two reasons. First, the uncertainty surrounding the interpretation of ECJ jurisprudence means that it is difficult for Member States to manage their healthcare systems properly and the necessary clarity could not be realised by Member States acting alone. Second, it is crucial to ensure that cross-border healthcare is as safe and efficient as possible but there is uncertainty about which country is responsible for what. Again, clarity cannot be provided without Community level action.
54. The Minister took the view that the general principle of healthcare in the draft Directive was that the standards of host Member States apply in their healthcare systems and that such an approach was in line with the principle of subsidiarity. (Q 85) In their Explanatory Memorandum, the Government said that the establishment of a clear framework for the provision of cross-border healthcare within the EU might require action at Community level but that it would be important to ensure that the level of detail did not go beyond what was necessary to achieve this objective.²³
55. Most of our witnesses agreed with the Government and the Commission that clarity about the provision of cross-border healthcare was required and therefore that Community-level action was justified (see paragraphs 21–25). However, a number of our witnesses emphasised the need to respect the principle of subsidiarity. The British Medical Association cautioned that the Directive must recognise the fact that healthcare systems differ considerably

²² SEC (2008) 2163, 02.07.2008 (pp16–18)

²³ Please see the Cabinet Office website: europeanmemorandum.cabinetoffice.gov.uk/search.aspx

across the 27 Member States. (p 117) The NHS Confederation warned that “any EU legislation ... should not interfere unduly with the organisation, funding, and delivery of healthcare, which remains a national competence.” (p 88)

56. UNISON expressed the view that the Directive undermined the principle of subsidiarity, explaining that, in reality, it was more than a framework for action. They were particularly concerned that the Directive would run counter to the NHS’s founding principles, “the system by which we ensure universality and equality of treatment for all”. (QQ 334, 338)

Overlap with Regulation 1408/71

57. In a number of places, the proposal states that the original texts of other instruments take precedence over this Directive. The most closely related piece of legislation is Regulation 1408/71 (see Box 1), which includes the “E112 clause” in its Article 22. According to Article 3(2) of the proposed Directive, the provisions of Article 22 of Regulation 1408/71, rather than of the Directive, would apply to cross-border healthcare when the conditions for its application are met (that is in cases of “undue delay”). When the E112 provisions are applied, the articles of the proposed Directive laying down the responsibilities of the Member States, information obligations and co-operation mechanisms would nevertheless continue to apply. The Commissioner took the view that the Directive as drafted is suitably clear as to how it could work in parallel with the existing E112 procedure under Regulation 1408/71. (Q 383)
58. A number of witnesses, though, were not convinced and expressed concern about the potentially confusing interaction between the two instruments. The Royal Pharmaceutical Society (RPS) “would like to see the interaction between the current regulation and this directive made explicit.” (Q 165) Without referring explicitly to the confusion between the two instruments, the Minister expressed the Government’s view that it was necessary for patients and governments to have a clear understanding of the rules that apply to cross-border healthcare. (p 16)
59. A lack of clarity over the concept of undue delay, which lies at the heart of the E112 procedure, was highlighted by witnesses as a reason for the confusion between the two instruments. The RPS stated that “a framework for determining what undue delay actually is” would be useful in order that patients were able to make an informed decision. (Q 165) The Government noted that the ECJ had stressed that decisions on “undue delay” 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 needed to be kept under review while the patient was waiting for treatment. (p 18)
60. The BMA agreed that the legal framework was confusing and required clarity, noting that the essence of the question was how to draw the distinction between the limited E112 right based on undue delay and the more general right under the draft Directive. They suggested that clarity might be so difficult to establish that “the E112 route may disappear if the Cross-Border Healthcare Directive is drawn sufficiently broadly” and they considered that this could successfully resolve the conflict. (QQ 317–318)

Conclusions and recommendations

61. Article 49, within which the freedom to receive healthcare services falls, forms one of the fundamental freedoms of the Community and is one of the key principles underpinning the internal market. Article 95 is the legal base for measures which have as their object the establishment and functioning of the internal market. Article 152(5) states clearly that Member States retain full responsibility for the organisation and delivery of health services and medical care. **We agree that Article 95 is the appropriate legal base for the Directive but emphasise the principle embodied in Article 152(5) and urge the European institutions to ensure that Member States' responsibility for the organisation and delivery of health services is fully respected in the negotiation and implementation of this Directive. Particular attention must be paid in that regard to the requirements laid down in Article 5 of the draft Directive.**
62. The Commission relies heavily in the draft Directive on delegation of the finer details to comitology committees. **We caution that delegated legislation runs the risk of creating rules that go further than intended by legislators, but we recognise that it is sometimes necessary. Recourse to the comitology procedure should be restricted to genuine and appropriate questions of detail, such as the provisions on the mutual recognition of prescriptions.** (See paragraph 161)
63. If Member States are to be able to organise and deliver their own health services and medical care, it is critical that they are able to manage the capacity of health services. **The recital in the draft Directive stating that Member States will have the right to refuse incoming patients is therefore welcome but would benefit from some strengthening and from clarification of the term "detriment".**
64. The freedom to receive healthcare services is protected by virtue of Article 49, TEC, and the stated aim of clarifying the European Court of Justice's rulings can only be pursued by Community level action. **We are therefore content that the proposal is consistent with the principle of subsidiarity as long as it does not go beyond the action required to clarify and to put into effect the principles laid down the by the ECJ.**
65. Regulation 1408/71 is closely linked to the draft Directive but we were concerned to learn that there is some confusion as to how the two pieces of legislation may interact. **We therefore urge that consideration be given to incorporating the relevant provisions of Regulation 1408/71 into the text of the Directive in order to clarify in which circumstances patients may be able to rely on those provisions rather than those of the Directive as currently drafted.**

CHAPTER 4: PRIOR AUTHORISATION AND PAYMENT

The issue

66. In this chapter we consider the central practical features of the system: prior authorisation by the home State, and payment. Issues include the merits of prior authorisation, the suitability of the definitions of hospital and non-hospital care and the need for a distinction between the two for prior authorisation. We also explore the potential created by the Directive for UK patients to “top-up” their medical care. This could occur in two ways: by patients paying the difference where care abroad is more expensive than in the home Member State or by paying for the prescription of an authorised drug that is not publicly funded in the home State.

Contents of the proposal

67. In the light of ECJ case law, the Directive provides that reimbursement for non-hospital care shall not be subject to prior authorisation, provided that if this care were carried out in the home Member State, it would have been paid for by its social security system.²⁴
68. However, the Directive permits Member States to implement a system of prior authorisation for reimbursement of the cost of hospital care provided in another Member State.²⁵ The Commission considers that the ECJ has recognised that the possible risk of seriously undermining a social security system’s financial balance or the objective of maintaining a balanced medical and hospital service open to all may constitute overriding reasons in the general interest capable of justifying a barrier to the principle of freedom to provide services.²⁶ The proposal introduces a minimum Community definition of hospital care (see Box 4), as no consistent definition of hospital care currently exists across the EU, and stipulates that prior authorisation must be non-discriminatory and proportionate.²⁷

BOX 4

Definitions of hospital and non-hospital care

Hospital care is defined in the proposed Directive as healthcare which requires overnight accommodation of the patient for at least one night or healthcare that does not require overnight accommodation but is included in a specific list (to be set up and regularly updated by the Commission). The Commission states that this list shall be limited to healthcare that requires use of highly specialised or cost-intensive medical infrastructure or medical equipment; or healthcare involving treatments presenting a particular risk for the patient or the population.

Non-hospital care is therefore all healthcare not requiring an overnight stay and not included on this list.

69. The Directive states that “Member States shall specify in advance and in a transparent way the criteria for refusal of the prior authorisation”.²⁸ It also

²⁴ (COM (2008) 414) Article 7

²⁵ (COM (2008) 414) Article 8

²⁶ *ibid.*

²⁷ (COM(2008) 414) Article 8 (4)

²⁸ (COM (2008) 414) Article 9(3)

stipulates that any administrative decisions regarding the use of healthcare in another Member State must be subject to administrative review and capable of being challenged in judicial proceedings.²⁹

70. On funding of treatment, the Directive provides that “The costs of healthcare provided in another Member State shall be reimbursed by the Member State of affiliation ... up to the level of costs that would have been assumed had the same or similar healthcare been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received.”³⁰

Merits of prior authorisation

71. The vast majority of the submissions we received supported prior authorisation. (QQ 2, 265, pp 62, 115, 157, 158) The Association of British Insurers stressed the importance of Member States’ ability to use prior authorisation to control costs and protect the financial resources of their health systems. (p 159) The Patient Liaison Group of the Royal College of Surgeons (PLG) stated that “If prior authorisation safeguards the stability of the healthcare delivery and the service in the home state, I think that is important and valid.” (Q 157)
72. The NHS Confederation, the PLG and the Royal College of Nursing (RCN) highlighted another benefit of prior authorisation, suggesting that it could help patients to make an informed decision as to whether to seek cross-border treatment. In particular, the RCN considered that it would give a patient the opportunity to explore some of the quality and safety issues involved with cross-border healthcare and to develop realistic expectations about what would be included in their treatment and what the long-term implications of this might be. (QQ 156, 265, 271, p 89)
73. Some witnesses identified the potential for such a system to be over-bureaucratic and consequently to delay the process for a patient seeking cross-border treatment. (Q 18) The PLG was concerned that prior authorisation could act as a barrier to an individual’s freedom to seek cross-border treatment; the Law Society suggested that the opportunities for Member States to erect administrative hurdles for the patient to overcome should be minimised. (Q 156, p 167)

“Hospital care” and “non-hospital care”

74. Several groups drew our attention to the potential for confusion over the term “hospital care”. (QQ 165,175, pp 133, 159, 167) The Royal Pharmaceutical Society considered that the definition as treatment requiring an overnight stay did not reflect the increasing volume of treatments being carried out as day cases or within primary care. (Q 175) The Commissioner stressed that the Commission “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”. (Q 378) This was criticised by UNISON as “meaning yet more significant powers for the Commission.”³¹ (pp 133, 134)

²⁹ (COM (2008) 414) Article 9(5)

³⁰ (COM (2008) 414 Article 6(2)

³¹ This comment refers to the comitology process, as outlined in paragraphs 50–51.

75. Several submissions questioned the need for a distinction between hospital and non-hospital care for prior authorisation. The NHS Confederation viewed the distinction as a false one and considered that prior authorisation should be required regardless of where care was delivered. However, they suggested that it should be for Member States individually to decide the circumstances under which prior authorisation would operate. (QQ 267, 270) The Association of British Insurers agreed that prior authorisation should be introduced according to the treatment required rather than the facility in which the care was to be provided. (p 159) The Law Society suggested that the draft Directive could usefully clarify whether “accommodation” meant within a hospital or, more broadly, within healthcare facilities. (p 167)
76. The Government disagreed with the Commission’s interpretation of the ECJ case law, insofar as the Commission have judged that non-hospital care is excluded from prior authorisation. (Q 55) The Royal College of Nursing presented a similar view “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”. (Q 271)

Payment upfront

77. Another issue highlighted by witnesses was the proposed system of patients paying for their cross-border treatment upfront and receiving reimbursement at a later date. The RCN believed this would affect the equity of the Directive as it would exclude from cross-border healthcare those without the financial resources to pay in advance. (pp 92, 117)
78. The Association of British Insurers suggested that prior authorisation should be the rule, not the exception, in order to avoid a situation where patients who had used cross-border healthcare and paid for this upfront, without first seeking prior authorisation, might be ineligible for reimbursement if their home Member State considered that payment for that particular treatment was not its responsibility. (p 159)
79. The NHS Confederation indicated that one of the benefits of prior authorisation could be to enable the patient, the local health authority and the clinician to discuss the costs involved, outlining what would need to be borne upfront and, within this, what the patient would be entitled to reimbursement for. (Q 245)
80. The RCN considered that where patients had sought prior authorisation, there ought to be the option of direct payment between Member States, and that this should be made explicit in the proposal. (Q 248, p 92) PA Consulting proposed a similar change to the Directive, or the implementation guidance, in order to clarify whether the payment system would involve a patient paying upfront and receiving reimbursement at a later date or the home Member State paying the host Member State directly. (Q 3)
81. The Minister expressed concern that if the Government were to issue money to individuals prior to treatment it would take them into some difficult areas with the potential for fraud. (Q 61) Commissioner Vassiliou stated that the Commission would want to see reimbursement for cross-border healthcare occurring only after the patient had been treated. However, she was clear that the Commission was not ruling out the option for home Member States

to transfer payment directly to the host Member State, but that this payment should follow treatment. (Q 386)

Top-up

82. Limiting reimbursement of costs to what would have been borne had treatment been delivered in the home Member State was widely supported by our witnesses. (pp 17, 54, 88–89, 115, 117, 159) However, the fact that this would leave patients to bear any additional costs that might arise from their cross-border treatment, and effectively “top-up” their care, was the subject of greater challenge. In particular, the Patient Liaison Group of the Royal College of Surgeons was concerned that meeting these costs would deter patients from seeking cross-border healthcare, a point echoed by the British Medical Association which suggested that this would damage equality of access. (Q 151, p 117) UNISON was more explicit in its criticism of the need for patients to meet any extra costs and suggested that this would create a two-tier system, impacting directly on the founding principles of the NHS and potentially resulting in legal challenges within the UK. (Q 334)
83. The Royal College of Nursing was concerned about the principle of top-ups and the inequalities they can create. In responding to Professor Richards’ review,³² they had “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.” In the cross-border context, they stressed that top-ups should not be allowed to spread across Member States without some form of public debate. (Q 250) Nevertheless, PA Consulting considered that “a degree of top-up probably is unavoidable” while the Royal Pharmaceutical Society (RPS) thought that the need should be minimised. (QQ 13, 179)
84. From the perspective of the potential for top-up with the EU-wide recognition of prescriptions, the Minister referred to Professor Richards’ report³³ which suggested that patients should not lose their entitlement to NHS care if they chose to buy additional care privately, as long as the private element of care would be delivered separately from NHS care. The Minister also informed us that the Government had published draft guidance making this principle clear for the NHS for consultation. (p 31)
85. The RPS highlighted another potential problem in topping-up, whereby “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.” (Q 188)

Private Medical Insurance

86. Article 2 states that the Directive “shall apply to provision of healthcare regardless of how it is organised, delivered and financed or whether it is

³² Letter from Professor Mike Richards: A review of the consequences of additional private drugs for NHS care www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_086036

³³ Improving access to medicines for NHS patients: a report for the Secretary of State for Health by Professor Mike Richards
www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_089927

public or private.”³⁴ Commissioner Vassiliou confirmed that it would be for the patient to decide whether to access cross-border treatment through public or private healthcare and that the Directive would apply to private insurance providers. This principle follows, she explained, from an ECJ judgment in 2007³⁵ in which the Court ruled that the Greek authorities should reimburse a Greek resident for the costs incurred when he was admitted to a private hospital in the UK. (QQ 386–388)

87. The Association of British Insurers (ABI) considered that the primary purpose of the Directive relates to State-provided healthcare. They had particular concerns about the possible increase in insurance costs that could be passed onto consumers through increased premiums. However, the ABI recognised that this point was UK-specific as in many other EU Member States consumers buy private medical insurance to complement or supplement their national health system cover. (pp 157, 158) The Minister stated that the Government were still consulting on the application of the Directive to private insurance and that they were having discussions on this point with the private insurance industry. (Q 49)

Conclusions and recommendations

88. **We think that a system of prior authorisation is necessary.** This will protect the financial resources of Member States’ healthcare systems. It will also allow clinicians to explain clearly to patients the treatment options available to them, including their respective advantages and disadvantages. This is particularly important to enable patients to make an informed decision and consider properly all of their treatment options and the corresponding practical arrangements, such as translation services (see Chapter 5).
89. A system of prior authorisation under which a patient is reimbursed after having made a payment in the host Member State raises issues of equity as it will exclude those without the necessary financial resources from using cross-border treatment. However, we recognise that issuing funds to the patient in advance of treatment could increase the risk of fraud, a risk that must be assessed by the Commission when reviewing the application of the Directive.
90. These issues could be tackled by providing that **once prior authorisation has been granted, it should be possible to transfer funds from the provider in the home Member State directly to the provider in the host Member State. However, in line with the principle of subsidiarity and given the different systems in use across Member States for payment, it is important that Member States maintain flexibility to decide whether to transfer funds directly.**
91. We are concerned that the definition of hospital care does not adequately reflect clinical reality across the EU and we query the need to distinguish between hospital and non-hospital care for prior authorisation in the manner proposed by the Commission. Instead, we suggest that the guidance of the European Court of Justice should be used, whereby prior authorisation can only be justified by overriding reasons of general interest. **In recognition of the different health systems and methods of financing across the EU and in line with the principle of subsidiarity, we recommend that it**

³⁴ (COM(2008) 414) Article 2

³⁵ Case C-444/05 Stamatelaki vs O.A.E.E [2007] ECR I-3185

should be for each Member State to decide when prior authorisation is required, subject to the principles laid down in the ECJ's case law.

92. **We agree that, where a prior authorisation system operates, patients must have a right of appeal in case prior authorisation is refused. This right will be distinct to each Member State and it should be clearly communicated to the patient, along with the procedure for exercising this right.** Failure to do so could constitute an unnecessary barrier to patients' rights to seek cross-border healthcare.
93. We recognise the potential for Article 6 of this Directive to impact upon the equity of cross-border healthcare and note that the prospect of additional costs may deter some people from seeking cross-border healthcare. **We consider that it is for Member States to determine the rules for "top-up" payments, both for medical care and for prescribed medicines.**

CHAPTER 5: COMMUNICATION, PROVISION OF INFORMATION AND LANGUAGE CONSIDERATIONS

The issue

94. In this chapter we consider the provision of information in cross-border healthcare—what this information should comprise, where responsibility rests for ensuring its availability and what issues might need to be addressed in its provision. We also explore how the issue of language variation across the Member States should be addressed in the cross-border healthcare context.

Contents of the proposal

95. Under the Directive, the home Member State shall ensure that there are mechanisms in place to provide patients on request with information on receiving healthcare in other Member States, and the terms and conditions that would apply, for example, when harm is caused as a result of healthcare received in another Member State. This information should be made easily accessible, including by electronic means, and shall include information on patients' entitlements, on procedures for taking up those entitlements and on systems of appeal and redress. Article 10, which sets down these requirements, also states that the Commission may develop a standard Community format for this information.³⁶
96. The Directive also proposes the establishment of national contact points to address information requirements. The form and number of the national contact points is to be decided by individual Member States.³⁷ Within the home Member State, the national contact point should provide and disseminate information to patients on their rights to cross-border healthcare and the processes involved in exercising those rights. They should also help patients to protect their rights and to seek redress where necessary.³⁸

Information: why it is needed and what it should cover

97. There was a general recognition of the need for provision of information on cross-border healthcare. (QQ 28, 118, 253, pp 53, 54, 91, 92, 168) In particular, information was required to enable patients to make an informed decision about whether to use cross-border care. PA Consulting highlighted that “people would make a choice on a small number of factors” and that, in the absence of real information, patients might make a choice that they would later regret. (Q 28) The Patient Liaison Group of the Royal College of Surgeons highlighted a current lack of knowledge about using cross-border healthcare and suggested that it “will only be an advantage if patients are given enough information on which to base their decision to seek treatment from another state.” (p 53, 54)
98. The Royal College of Nursing (RCN) highlighted the need for information for healthcare professionals as well as for patients; this was not explicitly addressed in the proposal. Given the role of health professionals in advising patients and

³⁶ (COM (2008) 414) Article 10(1), (2) & (3)

³⁷ (COM (2008) 414) recital 36

³⁸ (COM (2008) 414) Article 12

assisting in the interpretation of healthcare information, the RCN stated that it was important that this need was addressed. (Q 259, p 92)

99. There was a broad consensus that information provided to potential cross-border patients should include details about the processes involved (that is, how to navigate the system), eligibility, and likely costs and level of reimbursement. (Q 198, pp 17, 70–71, 92, 119, 159) This information should be easily accessible and understandable. (QQ 118, 133, pp 90, 92)
100. Several groups supported the provision of information on redress and complaints. (QQ 134–135, 201, pp 43, 70–71, 74, 119, 167–168) The British Medical Association (BMA) stressed that such information should also include details about the culture of care as this will differ considerably across Member States, on points such as whether the patient is expected to have family members present to offer some of the care. The BMA stated that “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.” (Q 296)
101. The Minister thought that the standard Community format, that the Commission may develop for information to be provided to patients, might only work for the basic and common details shared by Member States. She highlighted the variation between Member States’ healthcare systems and suggested that to try to capture all details on one form could prove to be difficult and unusable for patients. (p 30)

Information: responsibility for provision

102. There were differing views among witnesses as to where responsibility for provision of information should rest, and some were unsure; but we found little support for the proposals in the draft Directive. The British Dental Association, the Medical Defence Union and the General Medical Council all suggested that it should be for the Member State of treatment to provide information about its own healthcare. (QQ 116–119, 200, pp 73, 115) On the other hand, the Patient Liaison Group of the Royal College of Surgeons and the British Medical Association highlighted the potential for an EU-level responsibility in this area. (Q 147, p 119) This view was supported by the NHS Confederation’s assertion that it would be unreasonable to expect clinicians and local commissioners to give detailed advice on how other Member States’ systems operate. (QQ 254–255, p 90)
103. The Royal College of Nursing outlined a more collective form of responsibility within individual Member States involving three levels: practitioners; providers and commissioners; and Member States. They also suggested that “there would have to be some very comprehensive communication and training and development for people on the frontline ... 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.” (Q 256) This concern was echoed by the Medical Protection Society in relation to general practitioners: “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.” (Q 136)

Information: national contact points

104. Linked to the issue of responsibility for information provision is the proposed system of national contact points, which were largely supported by our witnesses. (pp 55, 90, 92, 105, 116, 119) Nevertheless, none of those we spoke to had a view on the exact nature of these national contact points, nor on where responsibility for their organisation, funding and delivery of information should rest. (QQ 133, 145, 147, 198–199, 200, 253–256, 295–296, 339–341)
105. The British Dental Association (BDA) and the NHS Confederation qualified their support. The BDA suggested that in the light of thirty years of freedom of movement of professionals it would be difficult to achieve the sharing of information between Member States, and the NHS Confederation highlighted that the national contact points could not give personal advice on the best care or act as advocates for individual patients. (pp 90, 105, 116) The latter point was also taken up by the Nursing and Midwifery Council which drew a distinction between types of information: national contact points could cover patients' rights, but information on treatment had to come from medical professionals. (Q 198)
106. UNISON highlighted national contact points as one of a number of measures that would place an additional administrative burden on the health systems of Member States. (p 134) In contrast, the British Medical Association welcomed the introduction of national contact points and stated that it was "pleased that this added administrative burden [of providing information] will not fall on medical professionals." (p 119)
107. The Commissioner explained that it would be for each Member State to decide how to organise their national contact point(s), including their number and location, with the flexibility to have regional contact points. She indicated that the Commission would have a role in helping with the management of the network of national contact points and agreed that the information provided across this network should be consistent. (QQ 381–382)

Information: issues to address

108. The General Medical Council, the Association of British Insurers and the NHS Confederation all stressed that no new costly, administrative burdens should be imposed on Member States or bodies within them through the information provision requirements. (pp 73, 90, 158) Moreover, the Minister and the NHS Confederation questioned how much practical information Member States would be able to provide about healthcare abroad. (Q 71, p 104) The NHS Confederation and the PLG suggested that vulnerable patients and those from lower socio-economic groups might require extra help or support in making the decision about whether to use cross-border healthcare. (pp 53, 105)
109. Several witnesses addressed the issue of the promotion of cross-border healthcare. The Minister stated that there was no obligation for Member States to promote cross-border healthcare and that the Government would not do so, though they would not attempt to keep information from patients about their rights. (QQ 69–70) The NHS Confederation also believed that the promotion of cross-border healthcare should not be an objective in itself. (p 88) However, the PLG suggested that awareness of cross-border healthcare could be increased through a national advertising campaign. Without such activity, the PLG stated that "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.” (QQ 149–150)

Language considerations

110. The variation in language across the Member States was highlighted as a potential barrier to the delivery of cross-border healthcare. (QQ 25, 79, 153–154, 168–169, 198, 220, 224, pp 54–55, 115, 118, 160) Two main areas were emphasised: the sharing of medical notes and patients’ medical records across Member States and the need for patients to give informed consent for treatment.
111. The British Medical Association (BMA) suggested that “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.” (p 118) This point was echoed by the Association of British Insurers and the Royal Pharmaceutical Society, who stated that “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.” (Q 168, p 160)
112. The BMA suggested that medical records should be kept in the language of the patient’s country of origin, highlighting the potential need for translation provision in Member States. (p 119) The Patient Liaison Group of the Royal College of Surgeons (PLG) was concerned as to whose responsibility it would be to ensure that patient notes and data are not misinterpreted. (p 55)
113. The British Dental Association (BDA), the Nursing and Midwifery Council and the General Medical Council focused on the need for a patient to understand the information being conveyed to them by the healthcare provider in another Member State in order to provide informed consent, a right which could not be waived by the patient. (QQ 198, 220, 224, p 115)
114. There were different views about who should be responsible for addressing the language barrier in cross-border healthcare. The Minister and the PLG both suggested that responsibility should rest with the individual. (QQ 79, 153, p 17) The Commissioner stated that responsibility should not rest with the host Member State and that where they had to pay for interpretation facilities they should charge for this service, leaving the home Member State or the patient with ultimate responsibility for the costs incurred. (Q 392) Similarly, the BMA believed that it would be unfair to burden the host Member State with the responsibility of language provision and suggested that further work was needed on this in the proposal. (p 118) By contrast, PA Consulting suggested that the host Member State should be responsible for the additional costs arising out of the language barrier, particularly in order to collate clinical information and obtain consent for procedures. In arguing their view, PA Consulting made the same suggestion as the Commissioner, whereby the host State would be entitled to incorporate the extra costs in its charge for healthcare services. (p 4)

Conclusions and recommendations

115. We believe that **the provision of accessible and comprehensive information to patients and medical practitioners is key to the success of the Directive**. Patients will only be able to make an informed decision on

whether to seek cross-border treatment if they have access to relevant information. Similarly, practitioners will need access to this information in order to advise patients appropriately. **We consider that the provision and financing of information must be the responsibility of the home Member State.**

116. The Commission proposes that the information provided should include details about receiving healthcare in another Member State, the terms and conditions that would apply, patients' entitlements, procedures for using those entitlements and systems of appeal and redress if the patient is deprived of such entitlements or harm is caused as a result of healthcare received in another Member State. **We agree with the Commission's suggestions about what information for patients should include. However, we recommend that a standard Community format for the provision of this information should not be drawn up.** The different procedures and processes that would need to be taken into account are numerous and we believe that this could result in the information being presented in a format that is difficult for patients to understand or use.
117. We consider that there is a lack of clarity in the Directive as to who is responsible for providing information on the service available in a particular Member State. **We recommend that the government of each Member State should be responsible for describing their own health system.** Furthermore, we consider that the exact role of national contact points in the provision and dissemination of information, and where responsibility for them should rest, should be clarified in the Directive.
118. The current lack of clarity over who is to provide what information, and how, creates the potential for this burden to fall primarily on medical practitioners. While their involvement may be beneficial for helping patients make an informed decision about cross-border care (see paragraph 72), **we recommend that the Directive makes clear that front line health providers giving this information to patients should be protected against complaints made against them if a patient suffers unexpected harm in the course of subsequent treatment abroad.**
119. Furthermore, we fear that the need to provide information and advice on cross-border treatment would interfere with the performance of practitioners' duties and could detract from the standard or timeliness of treatment of local patients. **We therefore recommend that the Directive should avoid the imposition of any administrative burden on healthcare practitioners due primarily to information provision obligations.**
120. It is clear that language may prove to be a barrier in the delivery of cross-border healthcare and that this may impact on a patient's choice to travel. We therefore consider that **patients must be made aware of any language issues and costs before they seek cross-border healthcare.** Language barriers could prove particularly critical in the areas of giving consent and ensuring continuity of care and patient safety. **We recommend that the responsibility for addressing the language barrier is decided by the home Member State.**

CHAPTER 6: PATIENT SAFETY AND THE PATHWAY OF CARE

The issue

121. In this chapter we discuss the issue of patient safety and, allied to this, the pathway of care, which represents a co-ordinated multidisciplinary approach to the delivery of healthcare for a patient. We consider how continuity of care can be ensured and how the effective exchange of patients' records and medical practitioners' fitness-to-practise information can be achieved across borders.

Contents of the proposal

122. The aim of the Directive is to provide a framework for the provision of safe, high quality and efficient healthcare.³⁹ The Commission recognises that it is vital to make certain that there are mechanisms for ensuring this quality and safety and that continuity of care between different treating professionals and organisations is an important aspect of this process.⁴⁰
123. The Commission acknowledges that ensuring continuity of care requires the transfer of relevant health data and, in particular, a patient's medical records.⁴¹ However, as highlighted in recital 17, the right to protection of personal data is a fundamental right recognised by Article 8 of the Charter of Fundamental Rights of the European Union.⁴² The Commission's consultation identified a concern that ensuring protection of personal data can hinder the appropriate transfer of medical records. The Directive therefore provides that this personal data should be able to flow freely from one Member State to another, while safeguarding individuals' fundamental rights.⁴³

The pathway of care

124. The importance of the pathway of care for patient safety was highlighted by the Patient Liaison Group of the Royal College of Surgeons (PLG), which suggested that because treatment often involves a series of procedures delivered by a multidisciplinary team, it is crucial to have someone with overall responsibility for managing the delivery of that care. Patients are not always aware of the pathway of care and tend instead to see their treatment as discrete packages of care. PLG considered that if patients sought a discrete piece of care abroad, they might then lose the continuity of care that the pathway provides. They also questioned how patients would get back onto the pathway of care on their return to the home Member State. (Q 143) The British Dental Association made a similar point in relation to dentistry, highlighting that this too is not often a "snapshot" event and that consequently seeking one-off episodes of care elsewhere can be very dangerous. (Q 298) Unite agreed that the pathway of care should address the needs of the individual from diagnosis right through to the post-treatment

³⁹ (COM(2008)414) Article 1

⁴⁰ (COM(2008)414) (pp9–10)

⁴¹ (COM(2008)414) (p12)

⁴² (COM (2008) 414) recital 17

⁴³ *ibid.*

- stage. This included the emotional and psychological well-being of the patient, which Unite suggested the Directive did not sufficiently take into account. (Q 371)
125. Conversely, the British Medical Association took the view that it would be possible for a pathway of care to be properly delivered under the Directive but suggested that certain differences across the Member States, such as the medical culture and language, would need to be addressed in order to ensure patient safety. (Q 298)
 126. It is equally important that clear responsibilities within the pathway of care are assigned. PA Consulting believed that it was unclear in the Directive how the dialogue and responsibilities for managing the patient pathway between the home Member State and the providing hospital would work. Providers needed to be clear about what was included, and excluded, from their responsibilities. (Q 3)
 127. Another important area of responsibility is follow-up care, both planned and, when treatment goes wrong, unplanned. The Association of British Insurers and PA Consulting suggested that greater clarification of responsibility for follow-up care was needed, though neither group specified where they thought this responsibility should rest. (QQ 31–32, p 158) The Minister also called for greater clarity, though she nevertheless confirmed that the UK NHS would, without question, treat any complications that might arise upon a patient's return. (Q 78)
 128. For Unite, UNISON and the Royal College of General Practitioners Northern Ireland Council this led to the logical conclusion that the package of care should be determined in advance of a patient receiving any medical treatment. The Royal College of General Practitioners stressed that this would be particularly important with complicated procedures. (Q 372, p 170)

Exchange of patient information: continuity of care

129. Handling of patients' records in cross-border healthcare is particularly sensitive. Patient information would need to be transferred between providers and commissioners and across borders and this would need to be done safely, completely and securely. As the RCN noted, this would be essential for the continuity of care. (Q 259)
130. The efficient flow of crucial information and the continuity of care could be particularly challenging on an EU-wide scale. In a cross-border setting there are obvious concerns that the threat of data misuse would also be increased. (Q 143, p 168) The Government indicated that they would be studying the implications of aftercare arrangements in the UK for clinicians, including difficulties that might be experienced in understanding case notes. (p 18)

Exchange of fitness-to-practise information

131. The exchange of fitness-to-practise information is essential in cross-border healthcare, an issue which a number of witnesses argued needed to be addressed in the Directive. For example, the RPS highlighted that Directive 2005/36/EC on the recognition of professional qualifications requires collaboration on information exchange across the Member States. However, they, along with the GMC, have found that some regulators are prevented from exchanging information because of rigid national interpretations of data protection legislation. Consequently, the RPS would "like it to be an absolute

requirement to share information and that regulators should disclose and exchange all relevant regulatory information.” (QQ 167, 211) The GMC also hoped that the new Directive would enable “blockages” to be overcome, suggesting that privacy legislation can be over-interpreted and is not always the impediment to sharing information that it is made out to be. (QQ 211–212) The Nursing and Midwifery Council argued that the diversity of standards within the EU meant that action was required at EU level. (Q 212)

132. The Royal Pharmaceutical Society and the General Medical Council highlighted a specific need for this exchange of information, whereby currently a doctor could be registered simultaneously in more than one country and could be subject to disciplinary proceedings in one of those countries. However, if that doctor was already registered in the UK, information on their fitness to practise would not routinely be sought and that practitioner might continue to practise in the UK despite having proceedings against them. (QQ 167, 211) Currently, the General Medical Council rely upon the country where the disciplinary action is being taken to notify them of these proceedings. Nevertheless, they stated that “we do not routinely receive information about the action taken against doctors in other countries”. (Q 211)
133. The General Osteopathic Council called for “a more robust European-wide approach to communication and information sharing (such as registration and fitness to practise data on healthcare professionals) between competent authorities.” (QQ 167, 193, 308, p 87, 165)

Conclusions and recommendations

134. We conclude that **clarity is required about the responsibilities of all those involved in the pathway of care.** This is particularly important in order to ensure patient safety and to enable patients to make an informed decision to seek cross-border healthcare, aware of who is responsible for every stage of their treatment and who will be accountable should anything go wrong along the pathway of care.
135. The secure and timely transfer of patients’ records across borders is essential for patients’ continuity of care. This may be problematic if case notes are recorded in different languages in the host and home Member State. **We recommend that a clearer system is established for the transfer of patients’ medical records.**
136. We note that Directive 2005/36/EC (see paragraph 131) on the recognition of professional qualifications requires collaboration on information exchange across the Member States. Nevertheless, we consider that without an obligation to exchange fitness-to-practise information this would not take place at a satisfactory or uniform level across all Member States and could result in problems such as medical practitioners with proceedings against them still being able to practise in other Member States where they were already registered. **We therefore recommend that Member States should be obliged to exchange information on medical practitioners’ fitness to practise.**
137. We note that over-rigid application of data protection rules has acted as an obstacle to such systematic sharing of information in the past. **We therefore recommend that the European Commission examine the extent to which data protection legislation may need to be amended in order to facilitate the exchange of information on fitness to practise, whilst minimising the threat of data misuse.**

CHAPTER 7: REDRESS AND INDEMNITY

The issue

138. In this chapter, we examine the draft Directive’s provisions for redress and compensation, including the provisions on clinical negligence insurance or indemnity (see Box 5).

The proposal

139. Article 5(1)(d) obliges Member 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. Under Article 4 of the draft Directive, “harm” is defined as “adverse outcomes or injuries stemming from the provision of healthcare”.
140. Article 5(1)(e) obliges Member States to ensure that systems of professional liability insurance “or a guarantee or similar arrangement, which are equivalent or essentially comparable as regards their purpose and which are appropriate to the nature and the extent of the risk” are in place for treatment provided in their territory.
141. A range of systems are deployed across the EU for the provision of indemnity arrangements, ranging from voluntary systems to mandatory systems that place the obligation either on individual practitioners or on the healthcare institutions. The position in the UK is explained in Box 5.

BOX 5

Clinical negligence claims in the UK

Under the Medical Act 1983 (Amendment) and Miscellaneous Amendments Order 2006, and the Dentists Act 1984 (Amendment) Order 2005, licensed primary care medical and dental practitioners must have adequate and appropriate insurance or indemnity cover, as explained below.

All clinical negligence claims against member NHS bodies in secondary care—care which is typically provided in local hospitals on referral from primary care—are handled by the Clinical Negligence Scheme for Trusts, which is run by the National Health Service Litigation Authority.

In primary care—care received on first contact with the medical system—medical defence organisations (such as the Medical Defence Union and the Medical Protection Society) offer one of the systems below, or a combination of both, against the cost of clinical negligence claims brought against primary care providers such as GPs and dentists.

Clinical negligence insurance provides a contractual right to assistance for professional negligence claims arising out of treatment in the primary care and independent sectors, subject to the terms of the policy. Financial limits are applied. Cover is provided on a “claims-made” basis, which means that existing members are entitled to assistance as long as they were a member at the time of the incident. Cover is discretionary for those who have ceased to be members.

Under a system of *discretionary indemnity*, cover is provided at the discretion of the indemnifying organisation and is not therefore guaranteed. There are no financial caps and it is offered on a “claims-incurred” basis which means that all claims that arise from any period when an individual was a member of the scheme fall within the cover even if the claim may be reported many years after they ceased to be a member.

142. The Medical Defence Union (MDU) outlined their understanding of provision in most other EU countries. In Austria, Germany, Latvia and France and Slovakia it is 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. In Italy and Estonia, insurance is voluntary. In Denmark and the Netherlands there is a state indemnity scheme. Sweden also has a state indemnity scheme but 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. Discretionary indemnity is allowed in the UK, Ireland and Malta. The MDU were unclear of the provisions in Greece, Luxembourg and Slovenia. (Q 108)

Redress

143. The importance of a system of redress was emphasised by a number of witnesses. The General Medical Council asserted: “there have to be effective systems that lead to regulatory action or redress for patients if they have been harmed.” (Q 192) The Medical Protection Society agreed and indicated that, in many European countries, “it is actually very difficult to bring a claim against a doctor.” (Q 127) UNISON warned that there was 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. (p 134) PA Consulting took the view that a proportion of cross-border healthcare procedures were likely to go wrong and, if it was not clear what would happen in those circumstances, “we would certainly be worried”. (Q 32)
144. Dawn Primarolo MP, Minister of State, explained, “Our view is that Article 5 is not clear enough with regards to how complaints, liability and negligence fit together”, although she agreed that patients would be subject to the systems in place in the host Member State. (Q 76) As such, she warned that UK citizens may not receive as much cover as they would expect in the UK and may therefore wish to insure themselves further. PA Consulting emphasised how critical the transparency of the complaint procedure was, and that patients must be aware of how to make a complaint. (Q 24)
145. The Minister added that clarification would be needed about how the home Member State might deal with problems caused in the host Member State. (Q 78) Similarly, the BMA suggested that the system of redress should allow for a mechanism by which the home Member State could claim compensation for the cost of rectifying clinical mistakes made by the host Member State. (p 119)
146. The importance of patient information on redress mechanisms was referred to by several witnesses (see paragraph 100). The British Medical Association wanted absolute clarity that redress could be obtained across international boundaries, and how that was done should be a clear part of the information available to patients. (Q 312) More specifically, the Law Society believed that the Directive should include an express information obligation on Member States, informing patients at the point of delivery of the appropriate avenue for complaints and judicial recourse. (pp 167–168)

Definition of “harm”

147. A number of witnesses questioned the definition of “harm” in the draft Directive (see paragraph 139), considering that it fails to distinguish between harm caused by poor care and accidental harm. The British Medical Association supported the amendment of the definition of harm along the lines of “avoidable adverse outcomes or injuries stemming from the provision of healthcare”. (p 130) They would ideally like to see such a definition accompanied by a “no-fault” compensation system that would provide for compensation in cases of accidental harm that were not related to poor quality or inappropriate care.
148. Contributors to the NHS European Office’s consultation on the directive also identified the definition of “harm” in the Directive as “very problematic”. The proposed definition should be replaced by a reference to “adverse events” or a definition based on avoidable incidents arising from negligence which resulted in serious harm. (p 112)
149. UNISON considered the Directive’s approach to redress and professional liability to be “too simplistic”. In their view, the Directive assumed that a health professional was always culpable, whereas the building or conditions in which the worker is providing services could have an equally important bearing on serious incidents taking place. (p 134)
150. The Commissioner confirmed that the intention of the Directive was not to cover unavoidable harm and that the Commission would have no hesitation in accepting an amendment to the Directive that would clarify this. (Q 396)

Provision of indemnity

151. The Medical Defence Union (MDU), which operates a system of insurance, took the view that patients rely on the state to ensure that there are adequate provisions in place for healthcare indemnity. It therefore considered 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.” (Q 99) The MDU concluded that all patients who are negligently harmed as a result of healthcare must be confident that they would receive compensation, regardless of the Member State of treatment. It did not consider that discretionary indemnity would meet the expectations of the majority of EU patients as it is only used in the UK, Ireland and Malta. (Q 108)
152. The MDU was concerned that the wording of Article 5(1)(e) could be interpreted as allowing discretionary indemnity to be used for clinical negligence claims. (p 36) By contrast, the Medical Protection Society (MPS), which operates a system of discretionary indemnity, was supportive of Article 5(1)(e) and considered that its construction “encompasses both insurance and other equivalent arrangements, such as discretionary indemnity.” (Q 120, p44) It was acknowledged by the MPS, however, that “discretionary indemnity is likely to be a concept that is not familiar to a number of Member States.” (p 44)
153. As the General Medical Council recalled, the UK Parliament discussed the merits of insurance and discretionary indemnity in the course of its debates⁴⁴

⁴⁴ For example, HL Deb 6 July 2006 cols 399–403

on the amendments to the Medical Act 1983 and the Dentists Act 1984 (see Box 5). When adopting that legislation, Parliament allowed the possibility of both insurance and indemnity, reflecting the fact that, in the UK, “there is a long history of successful protection of patients through indemnity as well as insurance.” (Q 225)

154. Some of our witnesses asserted that it was above all crucial to ensure that Member States maintained the right to determine their own mechanisms for patients to seek redress and indemnity if they were to suffer harm as a result of cross-border healthcare. (Q 130, p 157)

Conclusions and recommendations

155. The availability, and public awareness, of a transparent complaints and redress mechanism for patients is critical to the functioning of a cross-border healthcare system in the EU’s internal market. **We consider that not only should the Directive require a means of redress to be in place but that Article 5(1)(d) should be amended so as to require that the redress process be transparent and that patients must be aware of it. Information on the applicable redress mechanism should be made available to patients when investigating the possibility of securing healthcare treatment in a different Member State and responsibility for provision of that information should be made clear.**
156. The Directive does not provide clarity on how the home Member State might seek compensation from the host Member State for the cost of rectifying clinical mistakes made by the host Member State. **For the purpose of delivering cross-border healthcare, we consider it essential that the Commission examines how a home Member State may be able to claim compensation for the cost of tackling problems caused by clinical errors in the host Member State.**
157. The definition of “harm” in the draft Directive does not distinguish between harm caused by poor or negligent care and accidental harm. **We recommend that the definition be amended to ensure that it does not cover unavoidable harm. We would also emphasise that provision should be made for compensation in the event of accidental harm.**
158. It is important, as indicated in the draft Directive, that practitioners hold professional liability insurance or similar and it is also crucial that the principle of subsidiarity be respected. **We consider that the precise nature of the insurance system or similar is a matter for each individual Member State. However, we recommend that clear information on the systems chosen by each Member State must be made available to patients at the national contact point in the home Member State. This information should include the extent of insurance cover for institutions and practitioners and the implications of insurance systems for patients and practitioners.**

CHAPTER 8: CO-OPERATION BETWEEN MEMBER STATES

The issue

159. In this chapter we consider the Commission's proposals for increased co-operation between Member States. In particular we discuss potential problems with the cross-border recognition of prescriptions, such as language barriers, differences in drug names and the differing availability of medicines across Member States. We also examine some of the practical problems in respect of the interoperability of e-health systems and consider the merits of European reference networks.

Contents of the proposal

160. Article 13 of the Directive obliges Member States to co-operate with each other to the extent necessary for the implementation of the Directive.⁴⁵ The Commission considers that this requirement is necessary to facilitate co-operation between the providers, purchasers and regulators of different Member States in order to ensure safe, high quality and efficient care across borders.⁴⁶
161. The draft Directive provides for the cross-border recognition of prescriptions, so long as the authenticity and content of the prescription are clear. Any restrictions on recognition must be limited to what is necessary and proportionate to safeguard human health and must be non-discriminatory, or based on legitimate and justified doubts about the prescription's authenticity or content.⁴⁷ To facilitate this, the Commission intends to develop a Community prescription template and introduce measures to exclude specific categories of medicinal products from the recognition of prescriptions where this is considered necessary to safeguard public health.
162. European reference networks are also introduced under co-operation measures. The objectives of these include: providing healthcare to patients who have conditions requiring a particular concentration of resources or expertise; acting as focal points for medical training and research; facilitating information dissemination and evaluation; and providing quality and safety benchmarks.⁴⁸
163. E-health is introduced as another method of co-operation between Member States and consists of the provision of health services through the use of information and communication technology, where neither patient nor practitioner physically moves between countries. Member States are not obliged to introduce e-health systems or services, but the proposal aims at ensuring the interoperability of these systems where they do exist or are introduced.⁴⁹ Any measure adopted under e-health must respect the fundamental right to the protection of personal data in accordance with the

⁴⁵ (COM(2008) 414) Article 13

⁴⁶ (COM (2008) 414) (p18)

⁴⁷ (COM(2008) 414) Article 14

⁴⁸ (COM(2008) 414) Article 15

⁴⁹ (COM (2008) 414) recital 41

applicable law.⁵⁰ The proposal is without prejudice to the existing framework provided for by the Directive 2000/31/EC⁵¹, which ensures the free movement of information society services, including e-health services, between the Member States, and it will apply only insofar as the measures are not already covered by the existing Directive.⁵²

Cross-border recognition of prescriptions

164. The Government noted that they have recently amended medicines legislation to facilitate the mutual recognition of prescriptions. As a result UNISON questioned the need for prescriptions to be addressed in the Directive: “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.” (Q 350, p 19)
165. The Commissioner stated that while a rule already exists on the cross-border recognition of prescriptions “often we have problems in applying this rule because ... there are confusions, there are doubts as to the authenticity of the prescription, of the signature of the doctor and so on”. She went on to clarify that the Commission were aiming to use the Directive “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”. (Q 391)
166. The cross-border recognition of prescriptions was welcomed by several of the groups we heard from, including PA Consulting, the Nursing and Midwifery Council (NMC) and the Royal College of Nursing (RCN). (QQ 2, 202–203, pp 4, 93) However, all three groups qualified their support by highlighting areas where they felt greater consideration was needed.
167. In the view of the NMC, EU-wide prescribing would be difficult to achieve in practice due to the different languages and alphabets in use across the Member States—a point echoed by the General Medical Council who suggested that such differences would pose major challenges to patient safety. (QQ 202, 206–207) The Royal Pharmaceutical Society (RPS) noted that there may be difficulties in understanding prescriptions across borders due to differences in drug names and variations in the abbreviations used. One such example is a medicine with the generic name captopril, which is marketed in the UK as Acepril. However, if a prescription for Acepril was issued in Switzerland,⁵³ the correct generic name would be enalapril and if it was issued in Denmark, it would be called lisinopril. (QQ 168–169) A further problem is that different drugs are available in different Member States. (QQ 181, 349)
168. Another issue is that of nurse and midwife prescribers. As the RCN reported, the ability of nurses to prescribe medication for patients is limited to a minority of Member States: the UK, Ireland, Spain, Sweden and the Netherlands. (p 93) The NMC suggested that this would not be widely

⁵⁰ (COM(2008) 414) Article 16

⁵¹ Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (OJ L 178, 17.7.2000, pp 1–16)

⁵² (COM(2008) 414) (p 6)

⁵³ While Switzerland is not a Member State of the EU, the variation in drug names outlined here is likely to apply in many other Member States (as with Denmark in this instance) and to other generic drug names.

recognised across the EU and stated that they would like it to be ensured “that prescriptions written by an authorised nurse or midwife prescriber in the UK will be recognised in other Member States.” This view was shared by the RPS and the RCN. (Q 202, pp 64, 76, 93) In addition, the NMC suggested that this practice should be taken into account in any measure developing a Community prescription template. (p 76)

169. The RPS took the view that the Community prescription template would be advantageous and believed it was achievable, though they stressed that it would not necessarily mitigate the potential confusion over the different drug names used across Member States. (QQ 171, 177) The NMC echoed the concern that language could act as a barrier: “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” and suggested that EU-wide prescribing would be difficult to implement. (Q 202) The Minister suggested that templates could be fraught with difficulties as they implied vast systems that would make it difficult to maintain the planning of Member States’ health services. The Government also stated that they would need to consider whether the template would go beyond the information required on UK prescriptions. (Q 88, p 19)
170. It was also suggested to us that it might be difficult for those dispensing prescriptions to verify the legitimacy of the prescriber. (Q 205; p 64) The RPS believed “this would need web-based searchable registers of prescribers who are fit to practise in their Member State.” (p 64)

European reference networks

171. The NHS Confederation considered European reference networks an area of great interest, though they questioned the need for co-operation between Member States to be addressed in the Directive. “We have not yet seen evidence to suggest that it is necessary and appropriate to provide a legal basis for this work.” They also suggested that any work on co-operation should be project-based. They were considering the implications of the proposed co-operation measures in relation to subsidiarity. (Q 262, p 90)
172. The Government believed that the European reference networks were workable, but from the perspective of having participated in the European Reference Network pilot project, stated that “We support the aim of the reference networks but think their remit should be limited to covering treatment for rare diseases.” (p 19)
173. The Royal College of Nursing highlighted that “whether this Directive exists or not, there is much more collaboration taking place. There is a lot more collaborative research being undertaken, not to make everyone the same but to learn from experiences in other countries. That is a reality, whether this Directive is introduced or not.” (Q 263)

E-health

174. PA Consulting questioned the scope of the action outlined under the provisions for e-health. This area was probably “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.” (Q 33) This concern was shared by the Government, “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.” (p 19)

175. The importance of the interoperability of e-health systems was noted by a number of witnesses. The Royal College of Nursing (RCN) considered interoperability, particularly in relation to patient records, will have a significant impact on ensuring the safety and continuity of care (see Chapter 6). The RCN and UNISON cautioned that achieving interoperability among systems in the UK alone had proved difficult and believed that greater challenges would be faced in achieving cross-border interoperability, including language barriers and the use of different terminologies. (Q 262, p 134)
176. The RCN emphasised the need to identify examples of best practice for the interoperability of e-health and to share this across Member States. (Q 262) The British Dental Association pointed out that e-health is not particularly far advanced in dentistry and that opportunities in dentistry for e-health are currently underdeveloped as a result. (Q 307) The British Medical Association (BMA) stated that “It is very unlikely that e-Health systems will be fully interoperable by the time that this proposal is implemented across the EU.” (p 119)
177. Patient safety was another concern relating to e-health. The BMA was concerned that Article 16 of the Directive did not offer adequate protection for patients; “The BMA calls for the regulation of telemedicine⁵⁴ to be mentioned explicitly in this article. The BMA calls for doctors who undertake cross-border telemedicine ... to have the equivalent regulatory requirement to practitioners in the country where the patient accesses healthcare.” (p 131) The General Medical Council also wanted to see a responsibility on those placing the contract for the service to ensure that it could only be delivered in the distant country by properly qualified healthcare professionals. (Q 209)

Conclusions and recommendations

178. **Cross-border recognition of prescriptions is desirable**, particularly to ensure continuity of care for those who require follow-up treatment on returning home. While we recognise that this is already taking place (see paragraphs 164–165), **we recommend that the Commission develops detailed rules for this system to ensure that confusion is avoided, particularly in relation to language, the names of medicinal products and the verification of whether a prescription has been issued by a legitimate prescriber.** The consequence of not doing so would be to undermine the safety and easy accessibility of cross-border healthcare. We consider that common rules on the content and drafting of prescriptions would assist in overcoming this confusion. This need not imply the introduction of a common prescription template.
179. With or without the Directive, we note that collaboration between service providers across the European Union already takes place in order to share best practice. We nevertheless consider that European reference networks have the potential to assist the delivery of health services across borders and within each Member State. **We conclude that such networks may be**

⁵⁴ “Telemedicine” is defined in (COM (2008) 689) by the Commission as the provision of healthcare services at a distance, using electronic means of communication (either clinician to clinician or between clinician and patient).

most effective if they are speciality-based as this would allow relevant experience and best practice to be taken into account. We also believe it is important that the reference networks should not become overburdened by regulation. **We recommend that European reference networks could be a useful forum in which to develop EU-wide benchmarking on quality standards.**

180. It is clear to us that the electronic interoperability of systems is important, particularly to ensure continuity of care, but we note that this has proved challenging even within Member States. **We therefore urge the Commission and Member States not to underestimate the challenge of this task and to assess carefully the impact and modalities of introducing any system across the EU.**

CHAPTER 9: SUMMARY OF CONCLUSIONS AND RECOMMENDATIONS

Chapter 2: Overall objective and the need for action

181. Ten years of case law on cross-border healthcare have not provided the clarity needed by both patients and healthcare providers. We therefore agree that the main rationale for the Directive should be to clarify the application of treaty provisions to health services.
182. Whilst we recognise the need for action on these grounds, the response must strike a proportionate balance between individual choice on the one hand and effective delivery of public health provision, within limited budgets and reflecting different national and sub-national practices, on the other. Failure to strike a balance between these two objectives could be detrimental for all patients.
183. We take the view that the fundamental objective of the proposal should be to ensure that a framework is in place to deliver the availability of healthcare across borders but without excessive complexity and without harming the delivery of national health systems at a local level, and taking particular account of patient safety and redress.
184. We recall the set of overarching values underlying the delivery of health services throughout the EU that were agreed by EU Health Ministers in 2006 (see Box 2). This also finds expression in recitals 11 and 12 of the Directive. We consider above all that Member States must ensure that the principle of equity, within the terms of Member States' own health systems, underpins the negotiation and implementation of the Directive.
185. We note the argument that the introduction of patient choice may force hospitals to become much more responsive to patient needs and acknowledge that this may provoke adjustments to the services offered by Member States through the mechanisms and the incentives that choice creates. Choice is welcome if it has a positive effect on the efficient delivery of health services locally. In particular, we recognise that the proposal could have a positive effect where there are particular specialities with very long waiting lists. However, we recommend that effective delivery at the local level must remain a key objective.
186. It is clear that it will not be possible to identify the Directive's impact until it has been transposed. We therefore conclude that the Directive should be reviewed within three rather than five years after it comes into effect, in order that Member States can learn lessons from the experiences of cross-border healthcare sooner rather than later.
187. Given the importance of patient inflows and outflows to the stable and secure delivery of healthcare in Member States, we believe that the report produced by the Commission should include information on patient inflows and outflows.

Chapter 3: Legal and Regulatory considerations

188. Article 49, within which the freedom to receive healthcare services falls, forms one of the fundamental freedoms of the Community and is one of the key principles underpinning the internal market. Article 95 is the legal base

for measures which have as their object the establishment and functioning of the internal market. Article 152(5) states clearly that Member States retain full responsibility for the organisation and delivery of health services and medical care. We agree that Article 95 is the appropriate legal base for the Directive but emphasise the principle embodied in Article 152(5) and urge the European institutions to ensure that Member States' responsibility for the organisation and delivery of health services is fully respected in the negotiation and implementation of this Directive. Particular attention must be paid in that regard to the requirements laid down in Article 5 of the draft Directive.

189. The Commission relies heavily in the draft Directive on delegation of the finer details to comitology committees. We caution that delegated legislation runs the risk of creating rules that go further than intended by legislators, but we recognise that it is sometimes necessary. Recourse to the comitology procedure should be restricted to genuine and appropriate questions of detail, such as the provisions on the mutual recognition of prescriptions. (See paragraph 161)
190. If Member States are to be able to organise and deliver their own health services and medical care, it is critical that they are able to manage the capacity of health services. The recital in the draft Directive stating that Member States will have the right to refuse incoming patients is therefore welcome but would benefit from some strengthening and from clarification of the term "detriment".
191. The freedom to receive healthcare services is protected by virtue of Article 49, TEC, and the stated aim of clarifying the European Court of Justice's rulings can only be pursued by Community level action. We are therefore content that the proposal is consistent with the principle of subsidiarity as long as it does not go beyond the action required to clarify and to put into effect the principles laid down the by the ECJ.
192. Regulation 1408/71 is closely linked to the draft Directive but we were concerned to learn that there is some confusion as to how the two pieces of legislation may interact. We therefore urge that consideration be given to incorporating the relevant provisions of Regulation 1408/71 into the text of the Directive in order to clarify in which circumstances patients may be able to rely on those provisions rather than those of the Directive as currently drafted.

Chapter 4: Prior authorisation and payment

193. We think that a system of prior authorisation is necessary. This will protect the financial resources of Member States' healthcare systems. It will also allow clinicians to explain clearly to patients the treatment options available to them, including their respective advantages and disadvantages. This is particularly important to enable patients to make an informed decision and consider properly all of their treatment options and the corresponding practical arrangements, such as translation services (see Chapter 5).
194. A system of prior authorisation under which a patient is reimbursed after having made a payment in the host Member State raises issues of equity as it will exclude those without the necessary financial resources from using cross-border treatment. However, we recognise that issuing funds to the patient in

advance of treatment could increase the risk of fraud, a risk that must be assessed by the Commission when reviewing the application of the Directive.

195. These issues could be tackled by providing that once prior authorisation has been granted, it should be possible to transfer funds from the provider in the home Member State directly to the provider in the host Member State. However, in line with the principle of subsidiarity and given the different systems in use across Member States for payment, it is important that Member States maintain flexibility to decide whether to transfer funds directly.
196. We are concerned that the definition of hospital care does not adequately reflect clinical reality across the EU and we query the need to distinguish between hospital and non-hospital care for prior authorisation in the manner proposed by the Commission. Instead, we suggest that the guidance of the European Court of Justice should be used, whereby prior authorisation can only be justified by overriding reasons of general interest. In recognition of the different health systems and methods of financing across the EU and in line with the principle of subsidiarity, we recommend that it should be for each Member State to decide when prior authorisation is required, subject to the principles laid down in the ECJ's case law.
197. We agree that, where a prior authorisation system operates, patients must have a right of appeal in case prior authorisation is refused. This right will be distinct to each Member State and it should be clearly communicated to the patient, along with the procedure for exercising this right. Failure to do so could constitute an unnecessary barrier to patients' rights to seek cross-border healthcare.
198. We recognise the potential for Article 6 of this Directive to impact upon the equity of cross-border healthcare and note that the prospect of additional costs may deter some people from seeking cross-border healthcare. We consider that it is for Member States to determine the rules for "top-up" payments, both for medical care and for prescribed medicines.

Chapter 5: Communication, Provision of information and language considerations

199. We believe that the provision of accessible and comprehensive information to patients and medical practitioners is key to the success of the Directive. Patients will only be able to make an informed decision on whether to seek cross-border treatment if they have access to relevant information. Similarly, practitioners will need access to this information in order to advise patients appropriately. We consider that the provision and financing of information must be the responsibility of the home Member State.
200. The Commission proposes that the information provided should include details about receiving healthcare in another Member State, the terms and conditions that would apply, patients' entitlements, procedures for using those entitlements and systems of appeal and redress if the patient is deprived of such entitlements or harm is caused as a result of healthcare received in another Member State. We agree with the Commission's suggestions about what information for patients should include. However, we recommend that a standard Community format for the provision of this information should not be drawn up. The different procedures and processes that would need to be taken into account are numerous and we believe that

this could result in the information being presented in a format that is difficult for patients to understand or use.

201. We consider that there is a lack of clarity in the Directive as to who is responsible for providing information on the service available in a particular Member State. We recommend that the government of each Member State should be responsible for describing their own health system. Furthermore, we consider that the exact role of national contact points in the provision and dissemination of information, and where responsibility for them should rest, should be clarified in the Directive.
202. The current lack of clarity over who is to provide what information, and how, creates the potential for this burden to fall primarily on medical practitioners. While their involvement may be beneficial for helping patients make an informed decision about cross-border care (see paragraph 72), we recommend that the Directive makes clear that front line health providers giving this information to patients should be protected against complaints made against them if a patient suffers unexpected harm in the course of subsequent treatment abroad.
203. Furthermore, we fear that the need to provide information and advice on cross-border treatment would interfere with the performance of practitioners' duties and could detract from the standard or timeliness of treatment of local patients. We therefore recommend that the Directive should avoid the imposition of any administrative burden on healthcare practitioners due primarily to information provision obligations.
204. It is clear that language may prove to be a barrier in the delivery of cross-border healthcare and that this may impact on a patient's choice to travel. We therefore consider that patients must be made aware of any language issues and costs before they seek cross-border healthcare. Language barriers could prove particularly critical in the areas of giving consent and ensuring continuity of care and patient safety. We recommend that the responsibility for addressing the language barrier is decided by the home Member State.

Chapter 6: Patient safety and the pathway of care

205. We conclude that clarity is required about the responsibilities of all those involved in the pathway of care. This is particularly important in order to ensure patient safety and to enable patients to make an informed decision to seek cross-border healthcare, aware of who is responsible for every stage of their treatment and who will be accountable should anything go wrong along the pathway of care.
206. The secure and timely transfer of patients' records across borders is essential for patients' continuity of care. This may be problematic if case notes are recorded in different languages in the host and home Member State. We recommend that a clearer system is established for the transfer of patients' medical records.
207. We note that Directive 2005/36/EC (see paragraph 131) on the recognition of professional qualifications requires collaboration on information exchange across the Member States. Nevertheless, we consider that without an obligation to exchange fitness-to-practise information this would not take place at a satisfactory or uniform level across all Member States and could result in problems such as medical practitioners with proceedings against them still being able to practise in other Member States where they were

already registered. We therefore recommend that Member States should be obliged to exchange information on medical practitioners' fitness to practise.

208. We note that over-rigid application of data protection rules has acted as an obstacle to such systematic sharing of information in the past. We therefore recommend that the European Commission examine the extent to which data protection legislation may need to be amended in order to facilitate the exchange of information on fitness to practise, whilst minimising the threat of data misuse.

Chapter 7: Redress and Indemnity

209. The availability, and public awareness, of a transparent complaints and redress mechanism for patients is critical to the functioning of a cross-border healthcare system in the EU's internal market. We consider that not only should the Directive require a means of redress to be in place but that Article 5(1)(d) should be amended so as to require that the redress process be transparent and that patients must be aware of it. Information on the applicable redress mechanism should be made available to patients when investigating the possibility of securing healthcare treatment in a different Member State and responsibility for provision of that information should be made clear.
210. The Directive does not provide clarity on how the home Member State might seek compensation from the host Member State for the cost of rectifying clinical mistakes made by the host Member State. For the purpose of delivering cross-border healthcare, we consider it essential that the Commission examines how a home Member State may be able to claim compensation for the cost of tackling problems caused by clinical errors in the host Member State.
211. The definition of "harm" in the draft Directive does not distinguish between harm caused by poor or negligent care and accidental harm. We recommend that the definition be amended to ensure that it does not cover unavoidable harm. We would also emphasise that provision should be made for compensation in the event of accidental harm.
212. It is important, as indicated in the draft Directive, that practitioners hold professional liability insurance or similar and it is also crucial that the principle of subsidiarity be respected. We consider that the precise nature of the insurance system or similar is a matter for each individual Member State. However, we recommend that clear information on the systems chosen by each Member State must be made available to patients at the national contact point in the home Member State. This information should include the extent of insurance cover for institutions and practitioners and the implications of insurance systems for patients and practitioners.

Chapter 8: Co-operation between Member States

213. Cross-border recognition of prescriptions is desirable, particularly to ensure continuity of care for those who require follow-up treatment on returning home. While we recognise that this is already taking place (see paragraphs 164–165), we recommend that the Commission develops detailed rules for this system to ensure that confusion is avoided, particularly in relation to language, the names of medicinal products and the verification of whether a prescription has been issued by a legitimate prescriber. The consequence of

not doing so would be to undermine the safety and easy accessibility of cross-border healthcare. We consider that common rules on the content and drafting of prescriptions would assist in overcoming this confusion. This need not imply the introduction of a common prescription template.

214. With or without the Directive, we note that collaboration between service providers across the European Union already takes place in order to share best practice. We nevertheless consider that European reference networks have the potential to assist the delivery of health services across borders and within each Member State. We conclude that such networks may be most effective if they are speciality-based as this would allow relevant experience and best practice to be taken into account. We also believe it is important that the reference networks should not become overburdened by regulation. We recommend that European reference networks could be a useful forum in which to develop EU-wide benchmarking on quality standards.
215. It is clear to us that the electronic interoperability of systems is important, particularly to ensure continuity of care, but we note that this has proved challenging even within Member States. We therefore urge the Commission and Member States not to underestimate the challenge of this task and to assess carefully the impact and modalities of introducing any system across the EU.

APPENDIX 1: SUB-COMMITTEE G (SOCIAL POLICY AND CONSUMER AFFAIRS)

The Members of the Sub-Committee which conducted this inquiry were:

Lord Cotter (from December 2008)
 Lord Eames
 Baroness Gale
 Baroness Howarth of Breckland (Chairman)
 Lord Inglewood (from December 2008)
 Lord Kirkwood of Kirkhope
 Lord Lea of Crondall
 Baroness Morgan of Huyton
 Baroness Neuberger (until December 2008)
 Baroness Perry of Southwark
 Lord Trefgarne (until December 2008)
 Lord Wade of Chorlton
 Baroness Young of Hornsey

Declarations of Interest

Lord Eames

No relevant interests

Baroness Gale

Patron, Kidney Wales Foundation

Commissioner for Wales, Women's National Commission

Baroness Howarth of Breckland

Patron and Trustee, Little Hearts Matter

Deputy Chair, CAF/CASS (Children and Families Court Advisory and Support Service)

President and Trustee, Livability (formerly Grooms Shaftesbury)

Secretary, All Parliamentary Group for Children

Member, British Association of Social Workers

Associate, Association of Directors of Social Services

Lord Kirkwood of Kirkhope

Lay Member, General Medical Council

Lord Lea of Crondall

No relevant interests

Baroness Morgan of Huyton

Non-Executive Board Member of Southern Cross Healthcare PLC

Member Advisory Panel Lloyds Pharmacy

Member, UK Advisory Panel Humana Europe

Baroness Neuberger

Founder Member of advisory board to the Trustees of the Sainsbury Centre for Mental Health

Member, Central Ethical Compliance Group Unilever

Non-executive director VHI Health Insurance, Republic of Ireland

Member, Hon Fellowships of Royal College of General Practitioners

Member, Hon Fellowship Royal College of Physicians

Member, Hon Fellowship of Public Health Medicine

Member, Hon Fellowship of Royal College of Psychiatrists

Baroness Perry of Southwark

*Chair, Research Governance Committee of the Addenbrooke's Trust and
Cambridge University School of Medicine*

Patron, Alzheimer's Research Trust

Lord Trefgarne

No relevant interests

Lord Wade of Chorlton

No relevant interests

Baroness Young of Hornsey

Member, All Parliamentary Group for Humanists

Chair, Nitro Theatre Company

Board of Directors, South Bank Centre

Non-Executive Director, The National Archives

Patron, Josephine Wolf Trust

Patron, Post Adoption Centre

Patron, Action Space, visual arts and learning disabled people

Chair, Arts Advisory Committee, British Council

APPENDIX 2: LIST OF WITNESSES

The following witnesses gave evidence. Those marked with * gave oral evidence.

- Association of British Insurers
- * British Dental Association
- * British Medical Association
- * Rt Hon Dawn Primarolo MP, Minister of State, Department of Health
- * Commissioner Androulla Vassiliou, EU Health Commissioner European Commission
- Faculty of Pain Medicine of the Royal College of Anaesthetists
- Richard Fowler
- * General Medical Council
- General Osteopathic Council
- Law Society of England and Wales
- * Medical Defence Union
- * Medical Protection Society
- * NHS Confederation
- * Nursing and Midwifery Council
- * PA Consulting Group
- * Patient Liaison Group, Royal College of Surgeons England
- Royal College of General Practitioners
- * Royal College of Nursing
- * Royal Pharmaceutical Society of Great Britain
- * UNISON
- * Unite

APPENDIX 3: CALL FOR EVIDENCE

EU Sub-Committee G (Social Policy and Consumer Affairs) is conducting an inquiry into the issues raised by the European Commission's proposal for a directive on the application of patients' rights in cross-border healthcare. This was published on 2 July 2008. The relevant Commission document COM(2008) 414 final, together with an associated Impact assessment and other relevant documents, is accessible on the Commission website.⁵⁵

The Commission makes clear that the proposed directive would not undermine the existing rights of EU citizens to emergency medical treatment which may become necessary during a stay in another Member State or the existing rights to go to another European Economic Area (EEA) country for planned treatment, subject to prior approval by a local commissioner. These rights are currently established under EC Regulation 1408/71 on the co-ordination of social security schemes. In the UK, since January 2006, access to this entitlement has been made available through possession of a European Health Insurance Card (EHIC)⁵⁶, which replaced the previous E111 form.

The Commission recognises that the vast majority of EU patients prefer to receive healthcare in their own country but that, in certain circumstances, some patients may seek healthcare in another EU Member State. It reports that, in recent years, citizens have brought a series of cases to the European Court of Justice (ECJ) seeking to assert rights to reimbursement for such cross-border healthcare. In its judgments on these cases since 1998, the Court has consistently ruled that patients have the right in certain circumstances to reimbursement for healthcare received abroad that they would have received at home.

The Commission states that the purpose of their proposed directive is to provide a framework which makes clear how the principles which have arisen in these specific ECJ cases should be applied in general. The objectives of this framework will be:

- To provide sufficient clarity about rights to be reimbursed for healthcare provided in other Member States
- To ensure that the necessary requirements for high-quality, safe and efficient healthcare are ensured for cross-border care.

In order to achieve the objectives set out above, the Commission proposes to establish a Community framework for cross-border healthcare through the introduction of a Community directive. Subject to the conditions laid down in the text of the directive relating to the arrangements for prior authorisation and cost limit, the new directive would allow patients to seek healthcare in another Member State and to be reimbursed for the cost of this by the Member State of their origin (see Article 6 on pages 36 & 37 of the draft directive accessible through the link above).

The Commission states that the Community framework for cross-border healthcare should reflect the common values and principles in EU health systems which were agreed by EU health ministers in June 2006⁵⁷. These set out which

⁵⁵ http://ec.europa.eu/health/ph_overview/co_operation/healthcare/cross-border_healthcare_en.htm

⁵⁶ See the EHIC Information Service website—<http://www.ehic.co.uk>

⁵⁷ *Council conclusions on common values and principles in EU Health Systems—Outcome of proceedings*, Brussels, 5 June 2006 http://ec.europa.eu/health/ph_overview/co_operation/high_level/keydo_062006.pdf

Member State shall be responsible for ensuring the common principles for healthcare and what those responsibilities include, in order to ensure that there is clarity and confidence with regard to which authorities are setting and monitoring healthcare standards throughout the EU.

The Commission also states that the directive would establish a framework for European co-operation in areas such as: co-operation in border regions; recognition of prescriptions issued in other countries; European reference networks; health technology assessment; data collection; and quality and safety.

The Commission asserts that the legal basis for the proposed directive is provided by Articles 95 and 152 of the Treaty establishing the European Community (TEC)⁵⁸, which relate respectively to the establishment and functioning of the internal market, and to public health. The Commission states that the proposed directive fully respects the responsibilities of Member States for the organisation and delivery of health services and medical care.

The Commission goes on to argue that the directive respects the Community principle of subsidiarity⁵⁹ because both national government and individual citizens face challenges in this field that cannot be satisfactorily solved by Member States alone. It suggests that action by Member States alone, or lack of action at Community level, would significantly undermine the safe and efficient provision of cross-border healthcare, and would leave Member States without a clear capacity to manage and steer their health systems as a whole. It states, moreover, that the directive conforms to the Community principle of proportionality⁶⁰ because it leaves a wide margin for implementation by the Member States according to their national, regional or local circumstances and, hence, does not go beyond what is necessary in order to achieve its objectives.

Particular questions raised by the Commission's draft directive to which we invite you to respond are as follows:

- 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?
- 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?
- 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?
- 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?
- What conditions, if any, do you feel that Member States should be allowed to impose on citizens' rights to seek healthcare in another EU

⁵⁸ See Articles 95 (p.79) and 152 (p.114) of the Consolidated Treaties document in the link: <http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/ce321/ce32120061229en00010331.pdf>

⁵⁹ See Article 5 on page 46 of the Consolidated Treaties document in the link at footnote 4

⁶⁰ See Article 5 on page 46 of the Consolidated Treaties document in the link at footnote 4.

country—and to what extent do you think the draft directive satisfactorily makes provision for these conditions?

- 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?
- 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)?
- What is your view of the need to limit the medical conditions for which treatment could be sought in this manner?
- 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?
- 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?
- What are your views on the provisions set out in the draft directive for co-operation 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?

We also would welcome your views on any other aspect of the Commission's draft directive.

Interested parties are invited to submit a concise statement of written evidence to this inquiry by Friday, 26 September 2008.

APPENDIX 4: RECENT REPORTS

Recent Reports from the EU Select Committee

The Treaty of Lisbon: an impact assessment (10th Report, Session 2007–08, HL Paper 62)

Priorities of the European Union: evidence from the Minister for Europe and the Ambassador of Slovenia (11th Report, Session 2007–08, HL Paper 73)

The Commission's Annual Policy Strategy for 2009 (23rd Report, Session 2007–08, HL Paper 151)

Priorities of the European Union: evidence from the Ambassador of France and the Minister of Europe (24th Report, Session 2007–08, HL Paper 155)

Evidence from the Minister for Europe on the June European Council (28th Report, Session 2007–08, HL Paper 176)

Recent Reports prepared by Sub-Committee G (Social Policy and Consumer Affairs)

Session 2007–08

Increasing the supply of donor organs within the European Union (17th Report, Session 2007–08, HL Paper 123–I)

Protecting the consumers of timeshare products (3rd Report, Session 2007–08, HL Paper 18)

Session 2006–07

Proposal to establish the European Institute of Technology (25th Report, Session 2006–07, HL Paper 130)

Modernising European Union labour law: has the UK anything to gain? (22nd Report, Session 2006–07, HL Paper 120)