Government Response to the House of Lords European Union Committee report: 'Healthcare across EU borders: a safe framework.'

Presented to Parliament by
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Structure: The conclusions and recommendations from each chapter of the Committee's Report are reproduced with the Government response to each section given underneath. The only exception to this is Chapter 1, which did not contain any conclusions or recommendations. Here we simply comment on the introduction to the Committee's Report.

Chapter 1: Introduction

1.1 On 2nd July 2008, the European Commission published a proposal for a Directive on the application of patients' rights in cross-border healthcare. The proposed legislation follows European Court of Justice (ECJ) rulings on patients' rights to access cross-border healthcare. This includes the Watts case that directly concerned NHS services. The ECJ, in its judgment on the Watts case, concluded that NHS-type systems were subject to EU Treaty provisions, including Article 49 (freedom to obtain services). However, the ECJ did not pass judgment on whether or not "undue delay" applied specifically in this case or whether or not Mrs Watts was entitled to reimbursement from the NHS. These were matters left to the UK courts to determine.

1.2 The House of Lords European Union Committee published its Report on the European Commission proposal on 24th February 2009, *'Healthcare across EU borders: a safe framework'*. The Right Honourable Dawn Primarolo MP, Minister of State for Public Health, gave evidence to the Committee and the Government welcomes the Committee's Report.

1.3 The Committee considers that the proposed Directive is 'a justified and necessary attempt to codify 10 years of European Court of Justice case law'. The Government agrees that there is a need to codify existing case law to provide clarity about how the rules work in practice and to ensure that a sustainable framework for patient mobility is put in place that allows Member States to manage their health systems appropriately. The draft Directive the Commission has proposed will now be subject to change through a process of negotiation both within and between the Council of the European Union and the European Parliament.

1.4 *'Healthcare across EU borders'* identifies key issues that must be addressed by this Directive, and suggests how some of the challenges might be resolved. This Command Paper sets out the Government's response to the recommendations and conclusions within the report.

Chapter 2: Overall objective and need for action

Recommendations and Conclusions

- **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.**
- **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.**
- **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.**

2.1 The Government strongly agrees with the Committee that the objective of this Directive should be to provide clarity on how, under Article 49 of the Treaty establishing the European Community, patients can access healthcare in another Member State.

2.2 The Government also believes that the Directive must respect Member States' responsibilities for managing their own health systems. We are committed to ensuring that all patients can access high-quality care close to home. We therefore endorse the Committee's call for a proportionate response, balancing the needs of patients who choose to travel abroad for treatment with those of the vast majority of patients who choose to remain in their home Member State.

2.3 The Government agrees this proposal must not put in place a complex system for healthcare across borders or a system that damages Member States' health systems or parts of health systems. Member States should manage their healthcare systems, including on issues such as redress and safety standards.

- **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.

2.4 We support the Committee's recognition that the proposed Directive should reflect the overarching values agreed by Health Ministers in 2006, but re-emphasise that, as the statement of values itself makes clear, that EU legislation should not cover all of those principles.

2.5 It is crucial that we consider the many and complex ways this proposed Directive could impact on the principle of equity in healthcare systems. The equity of the vast majority of patients who choose to remain within their home health system is our key priority. See chapter 4 for more details of our response to this issue.

- **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.**

2.6 The Government shares the Committee's view that increased choice for patients may improve services for patients.

2.7 However, we endorse the Committee's assertion that effective delivery at the local level must remain a key objective for health systems. This Directive must reflect the fact that the key issue for most patients is having high quality services within their Member State, as locally as is possible.

- **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.**

- **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.**

2.8 We agree that, at this stage of negotiations, it is difficult to predict future demand for cross-border healthcare. Patients already have the right to access cross-border healthcare but uptake is low. However, once a final Directive is implemented there may be an increase in patients accessing cross-border healthcare in the medium to long term. The Government agrees it is very important that the proposed Directive creates a sustainable framework for patient mobility at a level higher than is currently the case. The impact of the Directive will need to be carefully assessed - but the Directive must not place disproportionate burdens on health systems in terms of data collection. With the proposal still under negotiation, and data collection requirements yet to be finalised, we consider it too early at this stage to set a timeframe or specific requirements for a report.

Chapter 3: Legal and regulatory considerations

Recommendations and Conclusions

- **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.**

3.1 As the current case law is about the freedom to obtain services, based on Article 49, and Article 95 is the legal base for measures that have as their objective the implementation of Article 49, we agree with the Committee that Article 95 is the correct legal basis for this Directive. We agree with the Committee that the final Directive must also take account of Article 152(5), which clearly states that Community action must fully respect the responsibility of Member States for the organisation and delivery of healthcare. We agree with the Committee that it is particularly important to recall Article 152(5) in relation to Article 5 of the draft Directive.

- **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).**

3.2 The UK Government shares the Committee's concerns on the extent of delegated legislation through Comitology committees. In the areas where the draft Directive envisages EU co-operation in healthcare, the Government notes that a range of work is already underway. We will be seeking to clarify the text of the Directive and to ensure that what is agreed in the final Directive is necessary over and above existing mechanisms. The scope of any Comitology must be clear, and limited to actions agreed by Member States as being necessary at an EU level.

- **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".**

3.3 The Government agrees that the principle in Recital 12 is welcome, and appreciates the inclusion of this by the Commission (Recital 12 states nothing in the Directive would force providers to accept patients for planned healthcare to the detriment of their own patients with similar health needs). Nevertheless, we also agree with the Committee that how healthcare providers in Member States can manage inflows of overseas patients needs further strengthening and clarification in the Directive, potentially including the term 'detriment'.

- **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.**

3.4 We agree that the creation of a legal framework to govern patients' freedom to obtain healthcare in another Member State requires Community level action. In our view, an EU Directive to achieve this is preferable to further ad-hoc European Court of Justice rulings. There are some additional proposals in the draft Directive on co-operation in healthcare, and we will be seeking clarity in the text on these areas, and to ensure what is proposed is in line with Article 152 and the principle of subsidiarity.

- **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.**

3.5 The Government agrees that it is not sufficiently clear how the initial draft of the Directive and the existing Regulation 1408/71 (which will become Regulation 883/2004/EC) interact. The final Directive should be clearer on this and we will be examining ways of ensuring such clarity.

Chapter 4: Prior authorisation and payment

Recommendations and Conclusions

- **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).**

4.1 We agree that a system of prior authorisation for hospital care is necessary to both protect Member States' healthcare systems and to ensure patients understand a) their healthcare and reimbursement entitlements, b) what they need to make an informed choice, and c) the necessary processes for safely accessing healthcare in another Member State. Like the majority who gave evidence to the Committee, we reject the Commission's view that prior authorisation is a block on cross-border healthcare, and believe that prior authorisation is necessary to make cross-border healthcare work effectively. For further details, see Chapter 5.

- **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.**

- **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.**

4.2 The Government is pleased that the Committee broadly agrees that it is for Member States to deal with the issue of equity. Given this, we do not think that the Commission has a role in assessing the increased risk of fraud caused by upfront payment.

4.3 We will be examining how best the UK can resolve issues around equity when the final Directive is published. However, we note that providing funds to all patients prior to treatment would not only increase the risk of fraud but could be inequitable for the majority of patients. A system of direct or upfront payment for all patients may destabilise the local healthcare systems that the vast majority of patients rely on, impacting on patients who cannot or will not travel for healthcare. Ensuring an equitable Directive means obtaining a Directive that prioritises the vast majority of patients who remain in the home system.

- **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.**

4.4 Existing case law developed the concept of 'hospital care', and recognised that prior authorisation can be applied to this concept. The Government believes changing this term, or trying to expand prior authorisation to cover 'non-hospital care', is unlikely to be achievable in this Directive. The Government agrees with the Committee that, in line with the principle of subsidiarity, and to reflect clinical reality on the ground, Member States should define what constitutes 'hospital care' within their system. We also believe, which we think is in line with existing ECJ case law, that Member States should have the freedom to operate prior authorisation as soon as they need to do so.

- **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.**

4.5 We agree with the Committee that patients must have a right to appeal if prior authorisation is refused. A fair and transparent system of prior authorisation for hospital care is essential for a system of sustainable cross-border healthcare. Patients should be made aware of the appeals process in their Member State of affiliation, but how the appeals process is handled by each Member State may legitimately differ.

- **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.**

4.6 The Government believes reimbursement should be limited to what the healthcare would have cost in the home state, or less where the actual cost is lower. The Government notes that the potential for additional costs associated with cross-border healthcare may deter some people from obtaining healthcare in another Member State, but believes its first priority must be to provide high quality services as locally as possible. The Government concurs with the Committee that it should be for Member States to decide any rules for patients wishing to have additional private care.

Chapter 5: Communication, provision of information and language considerations

- **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.**
- **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.**
- **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.**
- **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.**
- **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.**

5.1 We agree with the Committee that provision of information is the key to the success of the Directive.

5.2 The Government supports the call of the Committee for clarity in the Directive on the role of national contact points. In line with the Committee's report, we broadly agree with the list of information the Commission has proposed to require Member States provide to patients. National contact points should only be obliged to give this pre-defined set of information to patients seeking healthcare in their country, and provide sign-posts to patients on specific providers/sources for further information. We do not consider that each Member State should be required to provide information on other healthcare systems or providers in the other 26 Member States. We agree with the Committee that a standard community format for the provision of information is unlikely to meet the needs of patients (or health systems).

5.3 We believe the final text of the Directive on information provision must take account of differences in Member States' systems for example, there are devolved and local health systems within the UK. Member States' providers must also not be obliged to provide information to overseas patients that they would not provide to their own nationals, either directly or indirectly, as this is a disproportionate burden on them. National contact points should give background information, and providers should give information they would give to domestic patients, but the onus must be on the patient to be satisfied with the information they have.

5.4 We agree with the Committee that the Directive should not create additional obligations on healthcare professionals for patients within the Member State of affiliation. The national contact points could help fulfil a role here. Health professionals could suggest that patients who want to obtain cross-border healthcare seek further information from the national contact point.

5.5 We also believe this would help protect UK health professionals and bodies against liability claims from patients, which the Committee highlights as a potential risk.

- **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.**

5.6 The Committee is right to signal the importance of language issues in ensuring that patients give informed consent and receive appropriate continuity of care. Patients need to consider language issues carefully when deciding whether to obtain cross-border healthcare.

5.7 However, we do not think that a legal responsibility on Member States for addressing language barriers should be created in this Directive. Paying for translation services for patients who obtain healthcare in another Member Sate would constitute an additional cost for the NHS. There is no obligation on the NHS to pay or provide for translation services associated with the existing Regulation 1408/71 when patients get planned treatment in another Member State. In addition, where patients need to access emergency healthcare abroad using the EHIC system, we do not pay for translation services.

Chapter 6: Patient safety and the pathway of care

- **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.**

6.1 The Government believes the general principle in the draft Directive, that treatment takes place under the rules of the Member State of treatment, is helpful – and that responsibility for treatment of patients, whether domestic or cross-border, will be set out in the legislation of the Member State of treatment.

6.2 We also believe that local commissioners should be able to refuse to grant prior authorisation if there is clearly an inadequate pathway of care in cross-border healthcare. However, patients must understand that prior authorisation does not imply clinical approval of a patient's planned healthcare in another Member State, nor implies acceptance of any responsibility for that treatment, including where issues arise out of a poor pathway of care. It is the patient's responsibility to be aware who is accountable for assuring their safety throughout the course of their treatment.

- **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.**

6.2 While we are sympathetic to the need for secure and timely transfer of patient records, we are not convinced that the Directive can resolve these complex issues. Levels of cross-border healthcare are currently low and likely to remain low in the context of the millions of treatments that the NHS administers each year, while transferring patient records is a complex and potentially expensive task. However, the UK continues to support voluntary moves in this area – for example, in e-transfer there is already a pilot project underway looking at the electronic transfer of patient data within the EU for patients visiting another Member State who need urgent care (epSOS). This could provide the basis for further voluntary and Member State-led action.

- **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.**

- **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.**

6.3 The UK Government believes this Directive should focus as tightly as possible on the issue of codifying and clarifying existing case law on patient mobility. Therefore, though we continue to support sharing information on healthcare professionals' fitness to practice, we do not believe that this Directive is the appropriate vehicle for such measures. There is already an ongoing voluntary process around sharing healthcare professionals' fitness to practice data that the UK believes is creating helpful results, (e.g. the recent 'Portugal Agreement'[1]) and continues to support.

6.4 The Government agrees that if the Commission were to examine the issue of sharing information on fitness to practise data for healthcare professionals, this might include considering any necessary revisions to data protection legislation.

[1] The Portugal Agreement was agreed in autumn 2007 and is a collaborative voluntary work programme for professional healthcare regulators from within Europe. The Agreement sets out a range of actions that provide a framework for voluntary cooperation and the development of professional healthcare regulation in Europe throughout 2008 and 2009.

Chapter 7: Redress and indemnity

- **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.**

7.1 The Member State of treatment should be responsible for providing information to cross-border patients on their general redress system, via national contact points. The Directive should not allow EU judgment on what constitutes a 'transparent' system of redress, but be limited to making sure the information given to patients about redress in another Member State is itself transparent. Member States must ensure patients are provided with information on the redress mechanism. However, patients must ultimately be responsible for deciding that they have the information necessary to make a decision on accessing cross-border healthcare.

- **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.**

7.2 We firmly disagree that the Commission should be involved in examining how a home Member State may claim compensation for the cost of tackling problems caused by clinical errors in the host Member State. Ultimately, patients are responsible for pursuing providers in other Member States following negligent care. Although we are sympathetic to the argument that the NHS should be able to claw back costs due to negligent care in another Member State, this could be very difficult due to different legal systems and clinical realities. There could be a very large administrative cost for very small sums of money. If there is to be action on this, Member States should therefore lead in this complex area, not the Commission.

- **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.**

7.3 In our view, the existing definition of 'harm' in the draft Directive is not satisfactory and does not accommodate the differing legal systems in Member States. The current draft seems based on the 'no-fault' system of harm that is operated by some Member States, unlike the UK where the system is negligence based. 'No-fault' redress systems do not distinguish between negligent or accidental harm, as the Committee noted.

7.4 We will be seeking to amend the definition of harm in the draft Directive. We believe that the forms of redress that should be available, including the circumstances in which compensation is payable, should be determined in accordance with the Member State of treatment's legislation. The Government believes patients will need to be aware that different compensation systems will apply.

- **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.**

7.5 We agree with the Committee that this Directive should not infringe on the competence of Member States to set their own insurance schemes. It is for individual Member States to determine how their insurance systems (however defined) operate. We agree with the Committee that national contact points could provide clear information on the insurance systems operating in each Member State. We will be looking at the form this information could take and note the Committee's recommendation in this respect.

Chapter 8: Co-operation between Member States

- **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.**

8.1 As the Committee recognises, there are moves to ensure cross-border recognition of prescriptions issued by doctors in another Member State. However, there are varying arrangements in other Member States around allowing health professionals other than doctors to issue prescriptions. Given the differences in prescribing practice across the EU, it may be difficult to agree to anything further than the recognition of prescriptions by doctors. Further, we do not believe controlled drugs should be included in proposals on recognising cross-border prescriptions. On issues such as an EU-wide prescription template and e-prescription interoperability it is hard to see why the Commission should be able to introduce binding measures across all countries and all systems for what is a small number of prescriptions.

- **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.**

8.2 The Government agrees with the Committee that European reference networks have the potential to improve health services across the EU. However, we disagree with the Committee's belief that European reference networks could be a useful forum in which to develop EU-wide benchmarking on quality standards, as standards are part of Member States' competence. We agree that European reference networks should not be overburdened by regulation, and remain to be convinced that Comitology is necessary in this area. In addition, since there are existing European reference network pilots underway, it would seem sensible to wait until the pilots have been completed and evaluated before proceeding further on European reference networks.

- **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.**

8.3 We agree that any attempt to introduce electronic interoperability across Member States will be very challenging. Given the small numbers of patients who are expected to access cross-border healthcare, any action on interoperability must be proportionate, particularly given the expense and complexity of any health-related I.T. system. We will be seeking strong justification from the Commission about the broad nature of the text of the draft Directive which deals with this area.

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