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# Cross Border Healthcare & Patient Mobility

*Consultation on UK Implementation of Directive  
2011/24 EU (on the application of patients'  
rights in cross-border healthcare)*

## Cross Border Healthcare & Patient Mobility

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<b>For Recipient's Use</b>		

# Cross Border Healthcare & Patient Mobility

*Consultation on UK Implementation of Directive 2011/24 EU (on the application of patients' rights in cross-border healthcare)*

Prepared by the EU and International Cross-border Healthcare Team

# Contents

1. Purpose of Consultation.....	5
2. Introduction .....	6
3. Previous consultations & reference material .....	8
4. UK Devolved Administrations.....	8
5. Implementing Directive 2011/24 EU.....	11
6. Article by article discussion.....	11
Article 1 – Subject matter and scope.....	13
Article 2 – Relationship with other Union provisions.....	13
Article 3 - Definitions .....	13
Article 4 – Responsibilities of the Member State of treatment.....	13
Article 5 – Responsibilities of the Member State of affiliation.....	22
Article 6 – National Contact Points for cross-border healthcare .....	22
Article 7 – General principles for reimbursement of costs .....	26
Article 8 – Healthcare that may be subject to prior authorisation .....	28
Article 9 – Administrative procedures regarding cross-border healthcare .....	33
Article 10 – Mutual assistance and cooperation .....	42
Article 11 – Recognition of prescriptions issued in another Member State .....	44
Article 12 – European reference networks .....	46
Article 13 – Rare diseases .....	47
Article 14 – eHealth.....	47
Article 15 – Cooperation on health technology assessment.....	47
Articles 16-19 - Committee & delegated acts .....	48
Article 20 – Reports.....	49
Article 21 – Transposition.....	49
7. Annexes .....	51
8. Summary of questions for stakeholders .....	56
9. How to respond.....	56

# 1. Purpose of Consultation

- 1.1. This consultation document sets out the Government's approach to implementation of a newly adopted EU Directive on the application of patients' rights in cross-border healthcare. It seeks views on the detail of the implementation, and the accompanying impact assessments consider the effects the proposed approach may have on the UK and national health system(s).
- 1.2. The UK Government sees the Directive as a positive development which clarifies citizens' rights to access healthcare in another Member State of the European Economic Area (EEA)<sup>1</sup>, sets out the grounds on which they can claim reimbursement of the eligible costs of treatment from their home health system and is clear about the limits and conditions on reimbursement that Member States may place on patients who wish to access their healthcare in another EEA State. The Directive also sets out a number of areas for EU-wide cooperation in healthcare.
- 1.3. The purpose of the Directive is not to foster or promote cross-border healthcare but to facilitate the exercise of patient choice to access healthcare services in another Member State and to ensure that they are safe and of high quality when citizens decide to use the Directive's provisions to access necessary healthcare. The Directive also aims to help patients benefit from improved information and better clarity on the rules that apply.
- 1.4. Although there is a final adopted text for the Directive, it is for each Member State to decide how it is implemented at national level. There is considerable scope to decide how best to implement the Directive's requirements into the domestic system. This consultation document sets out the UK Government's overall approach to implementation, as well as how it proposes to meet the individual obligations contained within the Directive.

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<sup>1</sup> The Member States of the European Union plus Iceland, Liechtenstein and Norway

## 2. Introduction

- 2.1. The majority of EU citizens receive healthcare in the Member State where they live, via the health system through which they are covered or insured. However, in some instances, it may benefit the patient to obtain healthcare in another European country, where there may be better expertise available, lower costs, better availability of certain highly specialised treatments or where waiting times are shorter.
- 2.2. EU regulations on the coordination of social security systems (Regulation (EEC) 1408/71, which was replaced by revised provisions in Regulation (EC) No. 883/2004 with effect from May 2010) already provide certain levels of reciprocal healthcare cover to EEA citizens. These arrangements apply to tourists requiring necessary care when visiting another Member State, to people living and working abroad or, in certain limited circumstances, those who wish to travel specifically to receive healthcare. The Regulation also covers state pensioners, as social security provisions (including those for healthcare) are transferable around the EU at state pension age.

### *How the Directive evolved*

- 2.3. While these reciprocal arrangements have existed for many years, current generations of Europeans, accustomed to crossing borders with ease and being able to purchase goods and services from any part of the EU, are proving less willing to accept constraints on how and where they obtain their healthcare. This is often due to perceived advantages relating to quality, favourable cost, waiting times, the availability of different treatments or where citizens have close cultural or familial links in another country.
- 2.4. Over the last fifteen years, there have been more than a dozen high profile legal cases in which Member States' interpretation of the rules in respect of obtaining healthcare across borders has been questioned and on which the European Court of Justice (ECJ) has been asked to make a determination. The development of this case law based on individual cases (including one in 2006 against the UK in the case of *Yvonne Watts vs Bedford PCT*<sup>2</sup>, which the UK lost), was inevitably piecemeal and could not provide a coherent overall approach to patient mobility.
- 2.5. With so many ad hoc judgements being made in the courts, based on health systems which are very different in organisation and funding and leading to many grey areas because of these differences, the development of a Directive was seen as desirable to clarify the law and the rights of citizens across the EU. This new legislation reflects

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<sup>2</sup> Case C- 372/04 The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust and the Secretary of State for Health[2006] ECR I-4325 ("The Watts Judgement")

existing rights under the Treaties and the ECJ case law and applies best practice in providing access to these rights, The Council of Ministers and the European Parliament adopted the Directive on 9 March 2011. Its main objectives are to:

- Clarify and simplify the rules and procedures applicable to patients' access to cross-border healthcare;
- Provide EU citizens with better information on their rights;
- Ensure that cross-border healthcare is safe and of high-quality;
- Promote cooperation between Member States.

2.6. The Directive sets out the information Member States must provide for patients from other states considering coming to the country to purchase health care. It also sets out the arrangements that a Member State must provide to allow its own citizens to access their rights to reimbursement of the costs of cross-border healthcare if they chose to seek health care in another Member State. It also provides clarity on the information a Member State is required to provide to citizens of other states considering coming to their country. Crucially, the 'home' state retains responsibility for deciding what healthcare it will fund, so the Directive is not a way for citizens to gain entitlement to treatments that would not normally be available under their home health service. In addition, Member States are required to be clear and transparent in home legislation or administrative process as to what entitlements to healthcare home patients have within the national health system.

2.7. Member States' are required to transpose the Directive into national legislation by 25 October 2013 and this consultation seeks views on the shape of the Government's plans for transposition.

## 3. Previous consultations & reference material

### *The European Commission's original proposal for a Directive*

- 3.1. The Government consulted on the first draft of the Directive when this was first published in 2008. That consultation set out the rationale for the Commission's intervention in this area, the measures being proposed to make cross-border healthcare a success for European citizens and respondents were requested to contribute views to inform negotiations on the Directive.
- 3.2. The consultation documentation (including a partial impact assessment) and the Government's response to it are available to download from the Department of Health website at the following links:

[http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH\\_089029](http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_089029)

[http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/documents/digitalasset/dh\\_098387.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_098387.pdf)

### *House of Lords European Committee*

- 3.3. The House of Lords European Union Committee published a Report on the European Commission proposal for a Directive on 24th February 2009 - '*Healthcare across EU borders: a safe framework*'. This report sought to identify key issues that must be addressed by the Directive, and suggested how some of the challenges might be resolved. The Government's response to the recommendations and conclusions within the report is available to download from the Department of Health website at the following link:

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_098392](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_098392)

### *The NHS (Reimbursement of the Cost of EEA Treatment) Regulations 2010<sup>3</sup>,*

- 3.4. In 2009, the Government ran a limited consultation with the NHS on the scope and application of a set of draft regulations and accompanying directions [and guidance] to implement the judgment of the European Court of Justice in Case C-372/04 - the Queen on the application of Yvonne Watts v Bedford Primary Care Trust and the Secretary of State for Health.

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<sup>3</sup> S.I. 2010/915



- 3.5. This limited consultation sought to build on the full public consultation carried out in 2008/09 on the draft Directive and requested views from within the NHS on the establishment of prior authorisation and reimbursement arrangements in respect of applications from patients to access cross-border healthcare under the provisions of Article 49 of the Treaty. Following consideration of the consultation responses, the Regulations were made accompanied by directions and guidance. These came into force in April 2010. The consultation documentation is available to download from the Department of Health website at the following link:

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_107296](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_107296)

## 4. UK Devolved Administrations

- 4.1. This consultation paper gives the UK Government's perspective on how the Directive should be transposed into national provisions because it is responsible for ensuring that EU law is appropriately implemented across the UK.
- 4.2. Domestically, health is a devolved matter and Health Departments in England, Wales, Scotland, and Northern Ireland will be carrying out their own consultations to seek views on the Directive across the territories of the UK, as will Gibraltar<sup>4</sup>.
- 4.3. For details of the consultation in Scotland, please contact:

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For details of the consultation in Wales, please contact:

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For details of the consultation in Northern Ireland, please contact:

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<sup>4</sup> (Gibraltar is part of the EU as a "territory for whose external relations a Member State is responsible" – i.e. the UK)

## 5. Implementing Directive 2011/24 EU

### *Summary*

- 5.1. The Directive seeks to clarify the numerous case law precedents that have been established over a number of years by the European Court of Justice, as well as the rights of patients and duties placed on Member States in meeting those rights and expectations. It is necessary to ensure that, in transposing the Directive, these rights and duties are clearly set out and enforceable. However, it should be noted that the case law of the ECJ remains in force and may be used where challenges to the actions of Member States in relation to patients' rights to obtain healthcare in the EEA are made.
- 5.2. Member States are responsible for ensuring that their national legislation is consistent with European law. Where it is not, they must amend existing provisions and introduce new law where necessary. Where EU legislation has not been effectively implemented, Member States may risk legal action and corresponding financial penalties (known collectively as "infraction" proceedings).
- 5.3. This is a broad-based and complex Directive, covering all aspects of healthcare (but not long-term care which provides assistance with routine everyday tasks – i.e. social care). There needs to be correct implementation across the UK as a whole, and Gibraltar. Health is a devolved matter – therefore, the Government's aim is to ensure effective implementation whilst respecting the devolution settlements. The Department of Health is working closely with its counterparts in the devolved administrations and Gibraltar to coordinate the implementation. In addition, we must ensure that cross-border/patient mobility issues are properly taken account of within the reformed NHS in England.

### *What is needed*

- 5.4. From 1 April 2013, Primary Care Trusts (PCTs) will be abolished and the NHS Commissioning Board will take over responsibility for the aspects of patient mobility currently delivered by PCTs - such as making decisions on prior authorisation and reimbursing the costs of healthcare obtained in another EEA country. This is currently done under the arrangements in section 6A and 6B of the NHS Act.
- 5.5. Part 3 of the NHS Commissioning Board and Clinical Commissioning Groups Functions and NHS (Miscellaneous Provisions) Regulations 2013 makes provision for the exercise of the Secretary of State's functions by the Board and Clinical Commissioning Groups. The Secretary of State's duty to reimburse the cost of cross-border healthcare under section 6A and 6B of the NHS Act 2006 currently undertaken by PCTs is placed

on the Board. The Regulations require the Board to establish procedures for determining applications, require CCGs to supply information to the Board to enable the Board to decide applications and set out time limits. These Regulations will come into force on 1 April 2013.

- 5.6. A further set of regulations is required to implement the main provisions of Directive 2011/24/EU (the subject of this consultation). These will include provisions for Wales (Scotland and Northern Ireland will make their own legislation). Following consideration of responses to this consultation, the intention is that the England/Wales regulations will be made by the summer of 2013, to come into force on 25 October 2013 (the transposition deadline). The intention is to allow a period between the date on which the Regulations are made and published and the date on which the Regulations come into force, to allow for administrative preparations before the changes take effect on 25 October 2013.
- 5.7. These implementing regulations will not deal with the requirement for indemnity insurance or similar such arrangements in Article 4 the Directive, nor the Article 11 requirements on designation of special medical prescription and the non-exhaustive list of elements to be present on prescription forms. These will be delivered through separate implementing legislation and this work is being led by different parts of the Department of Health (albeit under the broad umbrella of Directive transposition) and is not part of this consultation.

## 6. Article by article discussion

### Article 1 – Subject matter and scope

- 6.1. Article 1 sets the overall scope of the cross-border provisions within the Directive, including the areas in which the Directive does not apply. These are:
- Long-term care;
  - Access to and allocation of organs (for transplantation);
  - Public vaccination programmes against infectious diseases (except with regard to Chapter IV via co-operation agreements).
- 6.2. The Directive covers treatment for long-term medical conditions (e.g. for dialysis, diabetes, epilepsy etc), which are in scope but not services which are described in our national arrangements as “social care” provision (e.g. personal care etc). Long-term care, in the sense of a service where the purpose is to support people in need of assistance with routine everyday tasks is specifically excluded from the scope of the Directive.

### Article 2 – Relationship with other Union provisions

- 6.3. This sets out the relationship with other EU Directives and Regulations and is a standard feature of most Directives. It is not necessary to include these references in the transposition Regulations.

### Article 3 - Definitions

- 6.4. Article 3 defines the terms used in the Directive. In preparing the draft Regulations to implement the Directive, these definitions have been used where appropriate. However, in some instances where there is existing domestic legislation we have used the appropriate language from that legislation.
- 6.5. As part of the implementing legislation, some of the Directive definitions will require further explanation to be understandable to domestic readers (e.g. “insured person” and “member state of affiliation”). The aim will be to make the domestic provisions as clear as possible for use within the NHS and by patients who are considering using these rights.

## Article 4 – Responsibilities of the Member State of treatment

6.6. Article 4 sets out the responsibilities of Member States where healthcare providers in their territory are providing treatment under the Directive. In the Regulations, we have used the term “visiting patient“ to describe a patient who is insured for healthcare in another Member State and is considering seeking healthcare in the UK under the provisions of the Directive. In this scenario, the UK would be the Member State of Treatment. In that circumstance, the Member State is responsible for ensuring that healthcare providers meet the following requirements:

- Provide patients with relevant information on treatment options and quality and safety;
- Provide clear invoices and price information;
- Apply fees in non-discriminatory manner;
- Ensure transparent complaints procedures and procedures to obtain redress;
- Apply adequate systems of professional liability insurance or similar;
- Respect privacy is respected in the processing of personal information;
- Supply patients with a copy of the record of their medical treatment.

6.7. On the face of it, these are comparatively routine requirements that most patients would expect to be in place for treatment provided in a foreign country. However, it is important to be clear about some specific points.

### *Scope*

6.8. Who is and who is not a "health professional" differs considerably across Europe. As an example, osteopaths are a regulated profession in only seven Member States throughout the EU (the UK being one of them). There is little in the way of consistency about who is and who is not regulated throughout Europe. The definition of “healthcare professional” in the Directive covers doctors of medicine, nurses, dental practitioners, midwives, pharmacists and persons considered to be a health professional according to the legislation of the Member State of treatment. Thus, where treatment is provided in the UK, the term will include any of the medical professions that are regulated in the UK.

6.9. The Directive defines “healthcare provider” by reference to the definition of “health professional” and “healthcare” in the Directive. Accordingly, the term “healthcare provider” means natural or legal person (for example a company) legally providing healthcare on the territory of the Member State. “Healthcare” is defined as health services provided by “health professionals” to patients to assess, maintain or restore

their state of health, including the prescription, dispensation and provision of medicinal products and medical devices.

- 6.10. The definition of “health professional” in the Directive is “a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Directive 2005/36/EC or a person considered to be a health professional, according to the legislation of the Member State of Treatment.
- 6.11. Therefore, in accordance with our national legislation regulating health professionals, the requirements on "healthcare providers" will apply to "healthcare" provided in the UK by any registrant of the following statutory healthcare regulators, whether as an individual or as an employee of a legal entity:
- General Chiropractic Council
  - General Dental Council
  - General Medical Council
  - General Optical Council
  - General Osteopathic Council
  - Health and Care Professions Council
  - Nursing and Midwifery Council
  - Pharmaceutical Society of Northern Ireland
  - General Pharmaceutical Council
- 6.12. A full list of the professions regulated by domestic legislation may be found at Annex A of this document.

### **Consultation question**

- Are there any other "health professions" in the UK to which the provisions of the Directive will apply when treatment is supplied in the UK?

### *Obligations on providers*

6.13. The focus of Article 4 then moves to how to ensure that the Art.4(2) obligations on providers (information on treatment options, quality & safety, pricing & invoices, complaints procedures, non-discrimination) are applied across the board – and what happens if these obligations are not properly observed. Here, we believe the requirements of the Directive can be met through the various existing requirements imposed by the statutory healthcare regulators and the Care Quality Commission (CQC), together with existing consumer protection provisions and that it is not necessary to make further provision in the regulations to implement the Directive.

### *CQC registration*

6.14. In England, providers are currently registered with the CQC if they carry out a 'regulated activity', whereas previously the qualification was based on providing a particular type of establishment or agency. This means that if a provider - whether public or independent/private - provides such a service, they are required to register with and be regulated by the CQC. The regulated activities are as follows:

- Personal care;
- Accommodation for persons who require nursing or personal care;
- Accommodation for persons who require treatment for substance misuse;
- Accommodation & nursing or personal care in the further education sector;
- Treatment of disease, disorder or injury;
- Assessment or medical treatment for persons detained under Mental Health Act 1983;
- Surgical procedures;
- Diagnostic and screening procedures;
- Management of the supply of blood and blood derived products;
- Transport services, triage and medical advice provided remotely;
- Maternity and midwifery services;
- Termination of pregnancies;
- Services in slimming clinics;
- Nursing care;



- 6.15. We believe that most, if not all, incoming cross-border patients wishing to use NHS facilities will fall into the above treatment categories and regulated activities. Thus, it appears that all likely healthcare providers - whether public, independent or private - engaging in/providing any service described above, are required to register with CQC and be bound by the relevant standards. In this, all of the Article 4 obligations map directly to CQC registration requirements, with the exception of professional indemnity insurance (however, see the discussion below on how the particular requirements of Art.4(2)(d) will be delivered).
- 6.16. Therefore, for all providers that are required to register with CQC, there is a mechanism in place to enforce these parts of the Directive - and this applies equally to providers regardless of whether they are state or private sector providers.

### *Health professional regulation*

- 6.17. While CQC registration provides a very high level of assurance within the system, CQC coverage will only apply to those providers that require CQC registration - not all do. The key area here is the regulated activity for CQC purposes of '*treatment of disease, disorder or injury*'. This is likely to be the principal area of activity in relation to cross-border healthcare and is defined with reference to the following healthcare professionals:

- |                         |                                     |
|-------------------------|-------------------------------------|
| - Medical practitioner  | - Nurse                             |
| - Dental practitioner   | - Midwife                           |
| - Dental hygienist      | - Biomedical scientist              |
| - Dental therapist      | - Clinical scientist                |
| - Dental nurse          | - Operating department practitioner |
| - Dental technician     | - Paramedic                         |
| - Orthodontic therapist | - Radiographer                      |

- 6.18. As a rule of thumb, services that do not involve these professionals but do include other healthcare professionals are likely to be outside of CQC regulation.

- 6.19. For the solution, we look to the further safeguards that are provided by professional regulation. The purpose of health professional regulation is to protect the public. Regulation ensures that those who practice a health profession are doing so safely. There are currently nine regulatory bodies. In total, they have over 1.4 million health professionals on their registers. The regulatory bodies have four main functions:

- Establishing standards of competence, ethics and conduct;

- Establishing standards for training;
  - Keeping a register of those who meet the standards;
  - Dealing with registrants who fall short of the standards required through fitness to practice action: e.g. by placing conditions on their registration or erasing them from the register.
- 6.20. The health regulators produce a variety of standards, guidance, codes of practice and codes of conduct that govern the way in which their registrants are required to act as a regulated professional. As such, health professionals are under a duty to abide by the terms and provisions of these documents. If they do not, and should a complaint be received about their conduct or performance, then the regulatory bodies can take account of whether the standards have been met when they decide whether it would be appropriate to take fitness to practice action to protect the public.
- 6.21. Thus, we believe that a very high level of regulatory coverage is ensured for cross-border patients seeking healthcare services in England. (It should be noted that CQC registration applies only to England - there are different models of system regulation in Scotland, Wales and Northern Ireland.)

### **Delivering the Article 4 obligations**

#### *National Contact Points – Art.4(2)(a)*

- 6.22. Article 4(2)(a) introduces the concept of National Contact Points (NCPs). This sets out that the NCP shall supply patients with “relevant information” on:
- Standards and guidelines on quality and safety in UK and Union legislation;
  - Provisions for the supervision and assessment of healthcare professionals;
  - Information on which health providers are subject to such standards and any restriction on practice;
  - Information on hospital accessibility for persons with a disability.
- 6.23. What is “relevant information” is not specified, in either Article 4 or elsewhere in the Directive. The idea behind NCPs is to establish a network of such bodies across the Community to facilitate patient access to information and services. To a large extent, this is an area where Member States will need to coordinate their approach, since a degree of uniformity of provision and practice across the Community will be required. We continue to have these discussions at European level.

- 6.24. Our proposed approach is to implement Art.4(2)(a) into domestic legislation almost as it stands, as a package of legislative measures aimed at setting the role and functions of the NCP (but see also discussion around Article 6 further on in this document). We would then provide detailed guidance on “how” the NCP will go about its business.
- 6.25. Our preferred approach to implementation is to reorder the provisions relating to the NCP scattered in articles 4, 6 and 10 of the Directive and group all these provisions on the role and functions of the NCP together in Part 2 of the Regulations (see also discussion around Article 6 further on in this document).

### *Pricing & how much to charge chargeable patients – Art.4(2)(b)&(4)*

- 6.26. The Directive requires healthcare providers to provide patients with clear information on prices and clear invoices. Providers cannot make up a price or seek to charge more simply because the person is an EEA patient seeking treatment under the Directive.
- 6.27. In terms of how these requirements are met, for secondary care provided by the NHS, relevant NHS bodies should recover the full cost of the treatment given to an EEA patient under the Directive, and this may include an element to cover reasonable costs of administration. Member States must have a transparent mechanism for the calculation of costs for cross-border healthcare which must be based on objective, non-discriminatory criteria known in advance. To calculate the cost, trusts should use the latest mandatory tariff or published national average reference costs at:

[www.dh.gov.uk/paymentbyresults](http://www.dh.gov.uk/paymentbyresults) [www.dh.gov.uk/nhs-costing](http://www.dh.gov.uk/nhs-costing)

- 6.28. A number of different methods for charging exist in primary care, where services are provided by GP practices, dental practices, community pharmacies and high street optometrists. There is no formal tariff classification in primary care, so the current system of patient charging will depend on the treatment or service that is required.
- 6.29. For GP and GP out of hours services, if an EEA national is treated as an NHS patient (as they should be unless they specifically request to be treated on a private basis), then that treatment / consultation is free of charge. Charges are, however levied for medication dispensed via community pharmacies. Charges for NHS dental services differ, in that they relate to average costs by treatment band for courses of treatment – that is, on the basis of a contract value, which is delivered through an agreed number of units of dental activity. These do not represent the average cost of treatment but the price the NHS is prepared to pay, which may be problematic in the context of reimbursing the NHS cost of equivalent treatment. We are working on solutions to this problem. The patient charge element of this depends on the level of treatment required and is set out at NHS Choices:

<http://www.nhs.uk/chq/Pages/1781.aspx?CategoryID=74&SubCategoryID=742>

- 6.30. Some groups of patients are entitled to free NHS sight tests and optical vouchers to help with the cost of glasses or contact lenses. Help with ophthalmic costs is categorised by the level of intervention required and the general rules are set out at NHS Choices:

<http://www.nhs.uk/NHSEngland/Healthcosts/Pages/Eyecarecosts.aspx>

*Private/independent providers*

- 6.31. An EEA patient seeking treatment in the UK may also wish to access services in the independent sector, which is not governed by the same charging principles as the NHS. Nevertheless, the Directive obligations on clear pricing apply equally to health care provided to a visiting patient by either the public or private sector. Where a Member State already provides for patients resident in the State with relevant information on these matters, the Directive does not obligate a Member State to provide more extensive information to visiting patients.
- 6.32. After careful consideration, we consider that the obligation on clear information on prices and invoices can be satisfied by our consumer protection legislation - in particular, the Consumer Protection from Unfair Trading Regulations 2008. These set out the rules that apply to consumer protection and the responsibilities on businesses to trade fairly. The Regulations implement the Unfair Commercial Practices Directive (2005/29/EC) in the UK and set a general duty not to trade unfairly, as well as ensuring that traders act honestly and fairly towards their customers. They apply primarily to business to consumer practices. If a trader misleads or otherwise acts unfairly towards consumers, then the trader is likely to be in breach of the Regulations and may face action by enforcement authorities (in the UK, the Office of Fair Trading). Both civil and criminal enforcement is possible under the Regulations.

*Non-discrimination*

- 6.33. Article 4 requires non-discrimination with regard to nationality; in particular, Art.4(2) requires the treating Member State to ensure that patients from other Member States are charged the same prices that apply to a domestic patient in a comparable situation. Healthcare providers must therefore apply the same scale of fees for healthcare to EEA patients as for domestic patients. If there is no comparable price for domestic patients, the price must be based on objective, non-discriminatory criteria (Art.4(4)).
- 6.34. This also means that independent providers who deliver NHS services will only be able to charge the same price as that for domestic NHS patients, should an EEA patient seek treatment as if they were an NHS patient. They will only be able to charge the patient as a private user if the patient has specifically asked to be treated privately. Providers cannot refuse to treat an EEA patient on the grounds of nationality but may do so where the delivery of such treatment would cause significant detriment to home

patients waiting for similar treatment or where there is insufficient capacity to treat additional non-UK patients.

- 6.35. The Equality Act 2010 prohibits direct or indirect discrimination in the provision of services (whether for payment or not) on grounds of race. Section 9(1) of that Act provides that “race” includes colour, nationality and ethnic or national origin.

### *Transparent complaints procedures – Art.4(2)(c)*

- 6.36. For NHS bodies, there is a central NHS Complaints Procedure, information on which is available through the NHS Choices website:

<http://www.nhs.uk/choiceintheNHS/Rightsandpledges/complaints/Pages/NHScomplaints.aspx>

- 6.37. Local NHS bodies will also have local complaints procedures for patients to access. Complaints about individual health professionals can also be made to the appropriate regulatory body.

### *Professional liability insurance – Art.4(2)(d)*

- 6.38. 4(2)(d) sets out requirements about systems of professional liability insurance (or similar such arrangement). This means that any health provider or individual health professional, not already covered by vicarious arrangements, must have an appropriate level of indemnity cover and make this known to the incoming patient. This is a policy area that has already been evolving separately in the UK following the 2010 “*independent review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional*”, chaired by Finlay Scott. The Government has accepted the recommendations of the review and the subsequent work to deliver the commitments in this area will ensure that the requirements of Article 4(2)(d) will be met in full in respect of individual professionals. This work is UK-wide in scope.

### *Personal data & patient medical records - Art.4(2)(e)&(f)*

- 6.39. The Directive requires the right to privacy with respect to the processing of personal data and that patients are supplied, on request, with a copy of the record of their medical treatment. That is, providing a copy of the record of treatment for the cross-border patient to take away (back to their own Member State for follow up with their own clinicians).
- 6.40. The Data Protection Act 1998 (as amended) provides safeguards on the protection of personal information and the right for a patient to request a copy of their health records. The right can also be exercised by an authorised representative on the individual’s behalf. This legislation is UK-wide in scope. Data Protection legislation defines a health record as a record consisting of information about the physical or mental health or

condition of an identifiable individual made by or on behalf of a health professional in connection with the care of that individual.

- 6.41. A health record can be recorded in computerised or manual form or in a mixture of both. It may include such things as; hand-written clinical notes, letters to and from other health professionals, laboratory reports, radiographs and other imaging records e.g. X-rays and not just X-ray reports, printouts from monitoring equipment, photographs, videos and tape-recordings of telephone conversations. Data Protection legislation is not confined to health records held for National Health Service purposes. It applies equally to all relevant records relating to living individuals; this includes the private health sector and health professionals' private practice records. The relevant guidance may be accessed here:

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_112916](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_112916)

### *Other general principles*

- 6.42. Article 4 confirms that the Member State of treatment is not required to provide treatment to anyone where this would undermine significantly the treatment of home patients. Art.4(3) also confirms that, where justified by overriding reasons of general interest (such as planning requirements or the wish to control costs), the Member State of treatment may adopt measures controlling access to treatment where this is necessary and proportionate. This could not be an arbitrary decision and would need to be supported by clear evidence on the effects of cross-border healthcare on the home system.
- 6.43. Member States may also provide information in other EU languages if they choose to do so. We propose covering all of these points in guidance.
- 6.44. Taken together, it is the Government's view that the comprehensive basket of provisions set out above meet fully the Directive's obligations on the responsibilities of the Member State of treatment.

## Article 5 – Responsibilities of the Member State of affiliation

- 6.45. Article 5 sets out the responsibilities of the patient's home Member State under the Directive. This includes the reimbursement of the eligible costs of cross-border healthcare and ensuring that patients are provided with information about accessing cross-border healthcare services. This is about making information on rights and entitlements publicly available and easily accessible, as well as the conditions that will apply to reimbursement and procedures for appeal and redress if patients consider that their rights have not been respected. Information about providers or services available in other Member States may also be facilitated via the respective National Contact

Points. As such, Article 5 is central in making the Directive workable and relevant for citizens.

- 6.46. It is critical here to remember that the Directive is about the rights of patients in exercising personal choice to go to another EEA country to access healthcare and seek reimbursement of those costs where the treatment in question would have been made available to the patient in the UK under the NHS. Importantly, it is not about the NHS formally commissioning healthcare for patients in other EEA Member States. Separate rules exist to regulate this - for example, when commissioners decide that a patient with a rare cancer should receive proton beam therapy abroad, as this technology is not yet available in the NHS.
- 6.47. In choosing to access healthcare in another Member State, the home patient is effectively stepping outside of the NHS system and using their rights under EU law to seek healthcare elsewhere. At this point, the patient is taking individual responsibility for ensuring that the service they obtain is appropriate and safe within the laws of the country of treatment (not under UK legislation). The NHS, under this legislation, will not be formally commissioning services from providers abroad and therefore will not be liable for the outcome of the treatment provided.
- 6.48. The implementing regulations will need to impose the duties set out in Art.5 on relevant NHS bodies, such as the NHS Commissioning Board and other bodies such as the National Contact Point.

### *Publicising information on rights*

- 6.49. In terms of making information on rights and entitlements publicly available, we will need to consider which are the most appropriate communication channels for UK citizens. In England, NHS Choices is central to how the Department of Health puts messages out to the general population and here we package Regulation 883/2004 and the Directive together in a comprehensive section on patient mobility and healthcare abroad:
- <http://www.nhs.uk/NHSEngland/Healthcareabroad/plannedtreatment/Pages/Introduction.aspx>
- 6.50. This will be revised to take account of the implementation of the Directive and to give greater emphasis on individual rights and the processes in place. The NHS Commissioning Board and NCP will also have a strong online presence from which information on the procedures and processes to follow may be publicised.
- 6.51. We will work with the NHS Commissioning Board to develop approaches to inform Clinical Commissioning Groups (CCGs), provider trusts, GPs and other primary care sources, to ensure that all parts of the health system respond effectively and appropriately to patient requests.

*Information on establishing entitlement(s)*

6.52. Aside from a general right to treatment in the EEA, the Government has clearly set out in the NHS Constitution a number of additional rights for NHS patients. It enables patients and their clinicians to make informed choices about the healthcare they need. The NHS Constitution includes the rights:

- To drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you.
- To expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you.

6.53. The legal basis for this right is currently set out in Directions from the Secretary of State to PCTs and SHAs. From 1 April 2013, this will be set out in the standing rules regulations, which will broadly replicate the current directions.

*Issues*

6.54. Article 5 requires health systems to respond, on request, with appropriate clarity about an individual's entitlement to services within the home system, as well as the terms and conditions that apply for reimbursement. The expectation is that there should be easily accessible published information providing clarity and transparency on entitlements for patients in making decisions about cross-border healthcare. Much of this information is already produced in the NHS in terms of treatment policies, criteria and thresholds for treatment. However, it is not easily accessible to patients and needs to be made available in an easily understood manner.

6.55. The NHS constitution right and the underpinning secondary legislation do not meet all the requirements of Article 5 – for example, as it stands, commissioners are required to make available information on their processes for decision-making, but not the resulting commissioning policies.

6.56. The Directive does not allow NHS patients to go anywhere within Europe and get any treatment (or drug) they may desire and then seek reimbursement from the NHS. Patients will only be eligible to receive reimbursement for treatments, products and services that would normally be provided by the NHS based on their clinical need. However, the way in which European law continues to develop suggests that countries which wish to refuse reimbursement for services they do not normally provide will need to ensure that their patients are well informed as to their healthcare entitlements.

6.57. The NHS does not have a defined list of healthcare to which all patients are entitled. NHS legislation is instead premised on providing a comprehensive range of services within a universal healthcare system where local commissioners make decisions on



what treatments should be prioritised for their local population, with a clear focus on commissioning for outcomes.

- 6.58. To avoid the risk of challenge in the future, the NHS will, henceforward need to provide patients with far greater clarity as to which services it does and does not fund. If information on entitlements is not publicised and patients challenge the NHS on the basis that they had no means of knowing whether a particular treatment method was not provided by the NHS, then it would not be possible to refuse them reimbursement in cases involving cross-border care. Therefore, to avoid uncertainty for patients, to meet transparency requirements and reduce the risk of legal challenge, commissioners will need to be clear to patients at the outset as to what types of healthcare they provide, or alternatively, what they do not provide.

### *Achieving clarity on patient entitlements in a reformed NHS (in England)*

- 6.59. In setting out the principles under which the NHS should provide clarity on entitlements to patients, we propose placing in the implementing legislation a broad legal requirement on both the NHS Commissioning Board and CCGs to provide information to patients on their rights and entitlements in relation to receiving cross-border healthcare, in accordance with directions made by the Secretary of State. The regulatory measure would set the basic legal framework for commissioners and associated Directions would set the detail of how the requirement should be met, including:
- The information to be provided, (this would need to include published information on services that are or are not generally available to NHS patients, including clinical and other access thresholds);
  - The form in which the information is to be provided;
  - The time limits by which it should be made available;
  - Training requirements for staff dealing with queries, and
  - Any other matter necessary to ensure they carry out this function appropriately.
- 6.60. The NHSCB and CCGs in the information they publish for patients could also provide information about how patients can get further information including details of who to contact. However, we cannot compel patients to have further discussions with any contact point (although we could certainly recommend that they do so).
- 6.61. Where commissioners have a policy on a treatment or service, they will be required to publish at least a summary of what this means for the patient in terms of entitlement – including any clinical or other criteria used to confirm that entitlement. Where commissioners do not have a policy on a particular treatment we would not seek to

require them to develop new policies about services they do or do not commission and nor could the patient be made to wait for weeks while one is written and agreed locally.

- 6.62. It is proposed that NHS Commissioning Board will act as a contact point for patients who cannot ascertain whether or not a treatment is available through a particular commissioner and CCGs will be required to confirm whether or not there is a policy or published information on the availability of the treatment sought to the Board. The Directions will cover what is specifically required, and we propose from the outset to do enough to ensure that patients can get the information they need easily without requiring commissioners to do more than is necessary to assure this.

### Consultation questions

- Do you agree that this broad requirement would ensure that the NHS is able to deliver the required clarity on entitlements and thereby respond appropriately to patient requests?
- If not, what additional measures should be considered to ensure that the NHS is able to deliver the required clarity on entitlements and thereby respond appropriately to patient requests?

## Article 6 – National Contact Points for cross-border healthcare

- 6.63. Article 6, requires Member States to set up one or more National Contact Points (NCPs) to carry out a range of functions in support of patients. The article needs to be read in conjunction with Art.4(2) and Art.10, which specify some of the information that the NCP must make available. Article 6 provides much more detail on the NCP's role and clarifies that it will also:

- Provide information including the right of a specific healthcare provider to provide services and any restriction on its practice ;
- Provide information about patients' rights and complaints procedures, mechanisms for seeking remedies and legal and administrative options to settle disputes, including in the event of harm;
- Provide patients and professionals with information on patients' rights and entitlements and terms and conditions for reimbursement including appeal and redress. (Information must make clear the distinction between rights under Reg. 883/2004 and the Directive);

- Ensure that information is easily accessible, available by electronic means and in formats accessible to people with disabilities.
  - Consult with patient organisations, health care providers and health care insurers;
  - Cooperate with other NCPs and the Commission and provide patients with contact details of NCPs in other Member States.
- 6.64. The NCP will act as a conduit or information point, providing a wide range of information and/or links to the required information (for example, via professional/registration bodies & regulators etc). The intention here is for Member States to work more closely together in the interests of patients. The information given by NCPs on quality of healthcare, patient safety and procedures to follow will help patients make an informed choice on the healthcare they seek. In delivering these responsibilities, the NCP(s) will need to have regard to the requirements of the Equality Act 2010 (which contains specific provisions for reasonable adjustments to be made by public bodies in respect of disabled persons).
- 6.65. The UK constituent territories of Scotland, Wales, Northern Ireland and Gibraltar intend to set up their own NCP arrangements and these will need to link together for the UK as a whole.

### *NCP England*

- 6.66. The Government has considered the most appropriate method for setting up a NCP in England. Due to the close links that exist between the work of the NCP and the NHS Commissioning Board in carrying out functions under Directive on behalf of the Secretary of State for Health, we propose that the NCP will be located within the NHS Commissioning Board. This will ensure compatibility of approach and secure the best delivery of the functions of the NCP for cross-border healthcare in England.
- 6.67. Nevertheless, it should be remembered that these are different functions. While the NCP will need good links with the policy and reimbursement sections of the NHS Commissioning Board, it will play no role in the decision-making mechanisms under the Directive, or in making recommendations on potential providers in other countries. Its role is the provision of information to patients - ultimately, the patient will need to decide how to use the information provided.
- 6.68. The NCP for England will need to be formally established via the implementing legislation. Additionally, as part of the implementing regulations, it will be more convenient for the reader if the responsibilities on NCPs, which are set out variously at Articles 4, 6 and 10, are grouped together in Part 2 of the Regulations.

### Consultation questions

- Do you agree that the NHS Commissioning Board is best placed to deliver the NCP function for England?
- What information, and presented in what format(s), do you think patients need to make an informed decision on receiving treatment in another EU Member State?
- What might be the impact of providing clear and transparent information on the volume of patients who may wish to access cross-border healthcare?

### Article 7 – General principles for reimbursement of costs

- 6.69. Article 7 requires the patient's home Member State to reimburse the cost of cross-border healthcare, subject to the derogations in Art.7(2), which deals with healthcare provided under Regulation 883/2004.
- 6.70. Article 7(2)(a) does not apply to the UK. The derogation at Art.7(2)(b) is a minor but complex adjustment in entitlements for pensioners residing in another Member State and is relevant to the UK. This essentially applies where the UK is what is termed the "Competent Member State" for a person in receipt of a pension (or a member of their family), who resides in another Member State; for example, a person receiving the UK state retirement pension who has retired to another Member State to live.
- 6.71. Broadly, when such an individual returns to the Competent Member State for a visit, then any healthcare obtained during a trip back (which is not subject to prior authorisation) shall be provided at the expense of the Competent Member State. "Pension" in this context includes the state retirement pension and also any long-term contribution-based social security allowance, such as Incapacity Benefit. This adjustment is reflected at s.9 of the implementing legislation.
- 6.72. Returning to the broader provisions of Article 7, this confirms that a patient can seek reimbursement for cross-border healthcare from their home state if the same or equivalent treatment or service would have been made available to the patient by the home state.
- 6.73. This means that a patient who is entitled to NHS care can seek reimbursement for treatment obtained in another Member State if the NHS would have provided the patient with the equivalent treatment. Conversely, if the treatment would not be provided by the NHS it will not be eligible for reimbursement under the Directive. Article 7(3) sets out that it is for the Member State to determine the health services it provides to patients. That determination may be made at national, regional or local level. Article 7(4) allows states to either reimburse the costs to the patient after treatment or, if the

State chooses to do so, pay the costs they are responsible for direct to the (EEA) provider.

- 6.74. Under Article 7(4), Member States may limit the amount of reimbursement to the cost of the treatment if it had been provided in the patient's home state. This is in accordance with existing domestic legislation, which enables reimbursement to be capped at the equivalent NHS cost.<sup>5</sup>
- 6.75. Nevertheless, under Article 7(6), Member States must also have a transparent mechanism for the calculation of costs of cross-border healthcare that will be reimbursed. Any calculation must be based on objective and non-discriminatory criteria known in advance.
- 6.76. Under Article 7(9), Member States may restrict reimbursement for overriding reasons of general interest if the demand for cross-border healthcare or certain specific services is undermining the home system. Use of this discretion would require robust evidence that the measure was necessary to ensure sufficient access to a balanced range of healthcare or to control costs and avoid waste of resources. We would need to be able to show that such a restriction was proportionate and not discriminatory. Given the requirements under other parts of the Directive on Member States to collect information, it is likely that any damaging high level of demand would become apparent relatively quickly.

### *What to reimburse*

- 6.77. Hitherto, the mechanisms for reimbursing patients are operated at local level by Primary Care Trusts in England and by Health Boards in Wales, Scotland and Northern Ireland. Following work done in 2009/10, England, Scotland, Wales and Northern Ireland all put reimbursement regulations in place. These measures provide the current basis in law to reimburse patients (subject to certain conditions) and limit the level of patient reimbursement to the cost of equivalent NHS treatment.
- 6.78. The Directive requires transparent and objective mechanisms for the reimbursement of patient costs and for the criteria for reimbursement to be known in advance. The mechanisms for calculating NHS cost will be dealt with separately by administrative measures but the Directive requires Member State authorities to be able to explain the reimbursement calculation and be able to justify it to applicants.
- 6.79. The NHS in England produces an annual national schedule showing the national unit cost of more than £53bn of NHS expenditure. National prices, based on these unit costs, are available for more than £28bn of NHS expenditure. These two publications cover the majority of treatments available across the acute sector. To achieve a standard national price, or cost where the price was not included in the tariff, it will be necessary to adjust the retrospective costs for inflation and/or efficiency requirements

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<sup>5</sup> Section 6A(8) of the National Health Service Act 2006 in respect of England

and also to add a national average value to both costs and prices for the Market Forces Factor.

- 6.80. In principle, we propose that reimbursement would be limited to the published national price which would be paid by a commissioner to a provider for an NHS service, or, where a price was not available, to the published national average cost. We already publish much of this information. However, we know that the NHS does not and will probably not have uniform costs for all services it delivers for some time. Where there is no price or published average cost and it would not be practical or possible to develop such a cost within the time limits, the NHS may have to reimburse the actual cost of treatment.
- 6.81. From 1 April 2013, Monitor will become the sector regulator for healthcare and will be responsible for regulating all providers of NHS-funded care. Under the provisions of the Health & Social Care Act, the NHS Commissioning Board will be responsible for tariff design and Monitor for calculating prices. Monitor has a legal duty to undertake consultation on prices and there will be an opportunity for reference to the Competition Commission where providers object to the way in which prices have been calculated. It is intended that tariff price-setting will become much more transparent in the reformed NHS.
- 6.82. Reimbursement of primary care treatments and services will need to take account of the different arrangements that apply to different services.

### *Calculating reimbursable costs*

- 6.83. Once the reimbursable items have been confirmed from receipts and any supporting documentation, there will be a need to calculate the cost of the same/equivalent treatment that would have been provided by the NHS and then compare this to the invoices and receipts. If the actual amounts paid for treatment in Europe were lower than the NHS costs, then the reimbursable amount is limited to the actual amounts paid (adjusted to take account of any deductible NHS charges in accordance with section 6A of the NHS Act 2006). If the actual amounts paid were greater than the calculated NHS cost (adjusted to take account of any deductible charges, etc.), then the calculated NHS cost is the maximum amount that may be reimbursed, in accordance with existing statutory provision.

### *Centralising functions*

- 6.84. For patients, there is a clear need to ensure that the process for determining entitlements and making decisions on prior authorisation and reimbursement is sufficiently transparent and timely. Those from the NHS involved in administering the reimbursement provisions must have a full understanding of the legal requirements placed upon them. Therefore, in implementing the Directive we propose to centralise the decision-making process on cross-border healthcare within the NHS

Commissioning Board. We believe this will ensure critical mass of expertise and consistency in decision making and application of the law.

6.85. In England, with effect from 1 April 2013, the NHS Commissioning Board will, as the centralised authorising and reimbursing authority take on the following responsibilities, hitherto delivered by PCTs:

- Receiving patient applications for authorisation under Regulation 883/2004 and reimbursement under section 6A of the NHS Act 2006 (the Article 56 provisions);
- Reimbursing patients their eligible costs;
- Considering applications for prior authorisation;
- Granting or refusing prior authorisation;
- Calculating reimbursement levels and informing patients about this;
- Dealing with appeals & reviews.

6.86. In addition, from 25 October 2013, the following additional duties:

- Publicising information on rights, entitlements and reimbursement principles, including which services patients will be reimbursed for;
- Discretion to make payment directly to overseas providers on behalf of the patient following treatment (where the Board is satisfied that this is justified in exceptional cases and in the patient's best interest);
- Data collection.

#### *Relationships with CCGs*

6.87. The NHS Commissioning Board will be directly responsible for commissioning a range of different services from primary care to specialised services. The function of deciding as to whether or not a patient should be reimbursed for accessing services in Europe is not part of the NHS's commissioning function and needs to be managed by experts efficiently. Therefore, the Board will be responsible for reimbursing the eligible costs for these services to patients in the context of cross-border care.

6.88. In addition, and by virtue of centralising the administration of cross-border healthcare, the NHS Commissioning Board will, from 1 April 2013 also be responsible for directly reimbursing the patient costs of other services normally commissioned by CCGs. To ensure the Board is not disadvantaged in carrying out this role, we will set out provisions in the NHS Commissioning Board and Clinical Commissioning Groups Functions and NHS (Miscellaneous Provisions) Regulations 2013 requiring CCGs to repay the NHS Commissioning Board for patient costs reimbursed on their behalf.

Good links between the NHS Commissioning Board and CCGs will also be necessary to ensure that clear information is available to patients about their entitlements and to enable swift determination in cases where prior authorisation is a consideration for access to cross-border healthcare.

- 6.89. We know that most people prefer to be treated close to home but DH is also aware of growing interest in the potential use by patients of their rights to access treatment in other EEA states. The Directive provides a means for enabling patients to make choices, which go beyond traditional borders. The system needs to be proactive and not defensive when responding efficiently to such requests. It is essential that the different actors in the system work together to the benefit of patients.

### *Equity*

- 6.90. One of the most evident potential inequalities arising from the Directive is the requirement that patients must pay in advance for their healthcare treatment within the EEA and then claim a reimbursement of eligible costs upon their return home. This clearly has the potential to exclude from accessing cross-border treatment those without the necessary financial resources.
- 6.91. For this reason, and building on the existing discretion of NHS commissioners we believe that it would be appropriate for the NHS Commissioning Board to be able to make payment directly to overseas providers on behalf of the patient following treatment – in effect acting as a third party – since this is allowable under the Directive. It is critical in allowing this that we do not invoke the NHS duty of care, as the NHS Commissioning Board will never be formally commissioning the treatment; they would simply be assisting the patient in exercising his or her individual rights.
- 6.92. This would not be the normal arrangement of preference under the Directive; we would expect most patients to pay the provider directly at the point of treatment and then seek reimbursement on return home. However, we believe that this is a discretion that should be available to the NHS Commissioning Board in exceptional cases where patients would otherwise face difficulty in meeting the cost of treatment in advance due to their financial circumstances. Any use of provisions to make payments direct to providers would be decided on a case-by-case basis and subject to satisfactory evidence that appropriate treatment has been provided. It would also be necessary for the provider and patient to agree to the NHS Commissioning Board acting as a third party and being in no way liable for the outcome of treatment.

### **Consultation questions**

- Do you agree that the NHS Commissioning Board should have discretion to make payments direct to overseas providers, where this would be beneficial for patients with



limited financial means?

- If so, what safeguards would you like to see put in place?
- How might any adverse impact be managed?

6.93. Article 7(4) goes further by allowing Member States to reimburse the full costs of healthcare plus “other related costs”, such as accommodation, travel and other expenditure that may be incurred by persons with a disability (e.g. in respect of an accompanying carer). However, the Directive recognises that this is a matter of discretion for Member States and that this may happen in accordance with existing national legislation. The Directive does not therefore create any new entitlements in these areas.

6.94. Each of the UK territories has arrangements in place for the consideration of travel costs and those of accompanying carers. Where the cost of travel would be met for patients who need treatment in the UK, this provision will also need to be available where the patient decides to seek treatment in another EEA state. Although accommodation costs are not generally provided for, these may be considered on an exceptions basis.

### Article 8 – Healthcare that may be subject to prior authorisation

6.95. Article 8 (1) allows Member States to operate a system of prior authorisation for healthcare that satisfies the criteria set out in Art.8(2). As a derogation from the primary purpose of the Directive, the way in which a system of prior authorisation is operated will be interpreted strictly by the Courts. Any system of prior authorisation and decisions to grant or refuse authorisation are restricted to what is necessary and proportionate. A blanket approach cannot be adopted nor can a system of prior authorisation be used to discriminate against patients or place an obstacle to the exercise of rights under this Directive.

6.96. Article 8 sets out the framework for the use of prior authorisation. If a Member State chooses to operate a system of prior authorisation, the Directive leaves Member States to decide the detail of how it will be operated within their territories, provided the system satisfies the above requirements. This has to be seen in the context that the current limited international evidence suggests that the majority of cross-border care is for services for which prior authorisation is not required. Member States which set up prior authorisation systems have to do this in line with the provisions of Articles 8 and 9 and ensure that their use and set up are objective, non-discriminatory, necessary and proportionate.

- 6.97. Currently, UK patients seeking treatment in another EEA Member State are recommended to contact their local NHS commissioner in advance of travelling to discuss whether prior authorisation is required, as well as what levels of cost reimbursement will apply. This should happen before the patient accesses treatment in another Member State, though retrospective applications may also be considered. Under Article 8(7) of the Directive, the NHS will have to publish clear information to patients as to which services come within the scope of prior authorisation and what the process is for applying for it. We will be able to advise patients to have a conversation with NHS experts but this cannot be mandated.
- 6.98. This process of authorisation enables the patient to confirm that they are entitled to the treatment requested, as well as the level of reimbursement they can expect. It also allows commissioners to ensure that patients are aware of all of the possible treatment options within the NHS, which may after all be more beneficial and convenient for the patient. However, this must not go beyond the provision of information on options - patients who insist on using their right to seek treatment in Europe are entitled to do so and to apply for reimbursement subject to the conditions and limits set out in legislation. Under existing legislation, reimbursement for certain types of specialised or cost intensive service is subject to a requirement that the patient has obtained prior authorisation. Authorisation must also be granted where the NHS cannot provide the treatment without undue delay.
- 6.99. Therefore, to ensure that the Directive provides a sustainable framework for cross-border healthcare and that Member States may manage their healthcare systems effectively and appropriately, the Government believes that prior authorisation systems are a sensible and necessary measure.
- 6.100. Where a Member State decides to adopt a system of prior authorisation, the categories of healthcare to which the condition applies must satisfy the criteria set out in Article 8(2), namely:
- (a) healthcare is made subject to planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, so far as possible, any waste of financial, technical and human resources and:
    - (i) involves overnight hospital accommodation of the patient in question for at least one night; *(e.g. specialist or some planned surgery)* or
    - (ii) requires use of highly specialised and cost-intensive medical infrastructure or medical equipment; *(examples here might be expensive diagnostic services, PET CT, MRI scans etc.)*
  - (b) involves treatments presenting a particular risk for the patient or the population; *(could include any treatment using e.g. radioactive isotopes)* or

- (c) is provided by a healthcare provider which, on a case-by-case basis, could raise serious and specific concerns relating to the quality or safety of the care with the exception of healthcare which is subject to Union legislation ensuring a minimum level of safety and quality throughout the Union *(this might be where there is specific evidence from a regulator that a provider has poor quality generally or outcomes in a particular procedure)*

6.101. The categories of healthcare selected by the Member State must be notified to the Commission and be made publicly available. It will be necessary to have robust evidence demonstrating that the categories of healthcare satisfy the criteria. Under current domestic legislation, in section 6A and 6B of the NHS Act 2006 the right to reimbursement of the cost of some healthcare, defined as a “special service” is subject to the condition of prior authorisation. The definition of a “special service” will need to be replaced to reflect the criteria set out above. The categories of healthcare to which a system of prior authorisation might apply are discussed at paragraph 6.120 below.

*Discretion to refuse prior authorisation in certain cases*

6.102. If we do continue a system of prior authorisation, refusal of authorisation is only permitted in four circumstances, which are set out in Article 8(6):

- (a) where the patient will, according to a clinical evaluation, be exposed with reasonable certainty to a patient-safety risk that cannot be regarded as acceptable, taking into account the potential benefit for the patient of the sought cross-border healthcare; *(this could be from poor quality care or unproven procedures)*
- (b) where the general public will be exposed with reasonable certainty to a substantial safety hazard as a result of the cross-border healthcare in question; *(this might include where a patient who had a highly contagious disease wanted to go to another state for treatment or where a patient with mental health problems and a history of violence requested authorisation)*
- (c) where this healthcare is to be provided by a healthcare provider that raises serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety, including provisions on supervision, whether these standards and guidelines are laid down by laws and regulations or through accreditation systems established by the Member State of treatment; *(this would require evidence from the appropriate regulator or authority)*
- (d) where this healthcare can be provided on its territory within a time-limit which is medically justifiable, taking into account the current state of health and the probable course of the illness of each person concerned.

6.103. The criteria (a), (b) and (c) above are relatively straightforward and uncontroversial, although they are really only seen as exceptional measures. For (c) in particular, it is

unlikely that this would ever be useable because it would require health systems to have defensible evidence about a lack of robust service regulation and quality failures by a provider in order to avoid challenge.

*Criterion (d) – refusal where treatment can be provided by the home State within a medically justified period of time (“no undue delay”)*

- 6.104. Criterion (d) above can be summed up as “*where there is no undue delay*” and is a complex matter which needs careful consideration. It essentially means that reimbursement of the cost of cross-border healthcare may be refused where the NHS is able to deliver the healthcare to the patient in a medically justified time period based on a clinical assessment of the individual patient’s condition and not merely by reference to a general waiting time.
- 6.105. The European Court of Justice, in previous cases (notably in *Watts vs the UK*) has said that refusal of prior authorisation is permitted where treatment can be provided within the home system in these circumstances. There is no doubt that some parts of the NHS may find it helpful to utilise this provision when treatment can be provided without delay as a way of limiting reimbursement expenditure. However, the Directive is clear that the use of the criteria is restricted and cannot be used as an unjustified obstacle to the free movement of patients. The Court of Justice has also confirmed that the unjustified use of systems of prior authorisation constitutes a barrier to freedom of movement and is contrary to European law.
- 6.106. Essentially, the Directive starts from the premise that the use of systems of prior authorisation is to be restricted to what is necessary and proportionate. The operation of a system of prior authorisation in accordance with the Directive should be seen as a two stage process.
- The first stage is to identify those categories of healthcare that we can demonstrate satisfy the criteria in Article 8(2) – i.e. subject to prior authorisation;
  - The second stage is to ensure that if we adopt the discretion to refuse authorisation where the NHS can provide the equivalent treatment “without undue delay”, then that discretion is operated correctly, in a proportionate manner and not in a way that undermines the purpose of the Directive.
- 6.107. The European Commission has indicated that it will be looking carefully at how both Article 8(2) and Article 8(6), particularly (d) are adopted by Member States, in order to ensure the provisions are not used as a blanket restriction on patients’ rights.
- 6.108. Research commissioned by DH and conducted over 2009/10 (by the Health Economics Consortium at the University of York) concluded that many NHS commissioners lacked understanding and clarity about patient rights under EU law and their entitlement to reimbursement. Centralising the decision making process will undoubtedly help to

ensure that future decision making is based on sound expertise but in a complex area we should be careful to ensure that restricted criteria for the refusal of prior authorisation are not used disproportionately.

- 6.109. In England, from April 2013, individual requests for treatment in other EEA Member States will be handled centrally by the NHS Commissioning Board. Centralisation of functions previously delivered on a piecemeal and variable basis by 151 PCTs provides for a process that will, we believe, deliver better management of administrative processes and help ensure consistency on a national basis of the application of the rules in such cases. However, to ensure this the Government is of the view that we need to go further and provide clarity to the system as to the limits of powers to refuse and what it must do when a decision to refuse is made.
- 6.110. In particular, where the criterion of “*where there is no undue delay*” was to be used to justify refusal of authorisation, it will be necessary for the decision to set out in full the reasons, explaining why the decision maker concluded that the NHS could provide the treatment within a medically justifiable period of time, based on an individual assessment of the patient’s case. We anticipate that in justifying the use of this criterion, the NHS would also be expected in each individual case to specify in writing the medically justified period of time during which treatment must be provided, based on an assessment of the individual patient and what would constitute undue delay for that patient. The ECJ has been clear that “undue delay” cannot be determined simply on the basis of general waiting time arrangements (whether national or local).
- 6.111. We take the view that providing this level of evidence on an individual, case-by-case basis would be burdensome on both clinicians and the NHS Commissioning Board, so there is a need to consider carefully how (or whether) we seek to make use of this criterion.

### *Options*

- 6.112. This is a complex measure and we recognise that there will be legitimate interests within the NHS and beyond on how (or whether) Art.8(6)(d) should be taken forward. We therefore seek views on the issue, with three potential options as follows:

#### Option [i]

##### **Adopt Article 8(6)(d) without limit**

- 6.113. This would require clarity and consistency in the application of the procedures to ensure that the refusal was appropriate, as well as careful record keeping. There would need to be proper consideration of each case and the reasons for any refusal fully set out. Given that the criteria cannot be used as a blanket restriction on patients, we have serious concerns that adoption without limit would lead to a tendency to ignore the

restrictions in order to limit the number of patients seeking to access their rights in line with waiting times at home.

- 6.114. The Directive is intended to allow patients to access rights under EU law on the freedom to obtain services. Waiting restrictions at home for the purpose of managing resources are not the key factor for determining undue delay. Therefore, in considering whether to adopt the provision without restriction, we need to consider whether it is necessary and proportionate approach, given that there are only small numbers of patients using their rights under EU law.
- 6.115. If the need for a restriction is because of a sudden and growing demand from patients for particular services, the NHS could seek to use the powers available at Art.7(9). This allows, in certain circumstances, and where evidence is available, a Member State to limit access to cross-border healthcare for overriding reasons of general interest. Alternatively, we might seek to add a service to the more restricted list of services set out at option ii.

Option [ii]

### **Adopt Article 8(6)(d) but apply it to a limited list of those services requiring prior authorisation and apply certain additional caveats on the system**

- 6.116. This option has potential and its application would be limited to a narrower list of services requiring authorisation, probably more specialist in nature. Applying the discretion to refuse authorisation to a more limited category of healthcare where it is necessary to have the discretion to refuse authorisation where the NHS can provide treatment would demonstrate that we are operating the system of prior authorisation narrowly. Taken together with carefully selected and justified categories of healthcare to which prior authorisation will apply, this should clearly demonstrate that in adopting this system we are taking a carefully balanced and proportionate approach. This option limits the administrative burden on the NHS and the restrictions on an individual patient's freedom to choose to obtain healthcare in another Member State and claim a reimbursement.
- 6.117. As described above, the NHS would also need to set out for each patient it wished to refuse, exactly what would from a medical standpoint represent "undue delay" in their individual case. This would be in order to avoid patients being refused authorisation but being forced to wait longer than medically necessary for treatment at home. The list of services subject to prior authorisation and the restrictions that apply would need to be developed and agreed, with the same safeguards applied as with option [i]. In providing evidence of the proportionality of refusal, the NHS would need to do the following:
- Consider the patient's medical history;

- Consider the extent of any pain, disability, discomfort or suffering that is attributable to the medical condition to which the service relates to;
- Whether any such pain, disability, discomfort or suffering makes it impossible or extremely difficult for the patient to carry out ordinary daily tasks;
- The extent to which the provision of the service would be likely to alleviate, or enable the alleviation of pain, disability, discomfort or suffering; and
- Set out what is the medically necessary time limit within which the treatment that the patient needs should be carried out (NB – this is not to be confused with waiting time limits or averages within the system which may not be appropriate in the context of the individual circumstances of the patient.)

### Option [iii]

#### **Do not adopt Article 8(6)(d)**

- 6.118. This preserves the central ethos of freedom of movement of EU citizens, which underpins this Directive. It would ensure that there was limited administrative risk of the NHS imposing unreasonable restrictions on patients, which would constitute obstacles to the freedom of movement of patients. If patient demand were ever to become higher than anticipated (so that it destabilises the system), the Government could consider seeking to use the powers available at Art.7(9).
- 6.119. The Government's view is that we could either adopt option [ii], with a limited list of services for prior authorisation and clear evidence to patients' as to why they might be refused authorisation, or option [iii], where we would not adopt the provision and therefore might have a more extensive list of services within the system of prior authorisation, as a preferred option.
- 6.120. If option [i] were adopted, we are doubtful whether in practice it would be operated satisfactorily with each decision taken on the basis of the individual patient's clinical needs and in a proportionate manner bearing in mind the overall purpose of the Directive to facilitate a patient's right to choose to obtain healthcare in another Member State. We would welcome your views on the three options.

### Consultation questions

- Do you have a view on whether or how the Government should adopt the derogation Art.8(6)(d) derogation?
- Should the derogation (if taken) be limited to the list of highly specialised services only?
- Do you believe this Article can be made to work in practice without being unduly burdensome?

#### *Categories of treatments subject to prior authorisation*

- 6.121. Where the home Member State exercises the discretion to have a system of prior authorisation, Article 8 requires that the home state must notify the European Commission of the categories of healthcare subject to prior authorisation and to make this information publicly available to citizens.
- 6.122. For the categories of "treatments subject to prior authorisation", Member States would need to show that a convincing methodology has been used for determining this. The Commission will be reviewing those services requiring authorisation and will challenge Member States that seek to restrict the freedom of individuals to obtain services where this is done in an arbitrary or inappropriate way. It is therefore necessary to establish a reasoned and justifiable starting position.
- 6.123. We take the view that prior authorisation will not be applicable generally to services such as primary care, dentistry and ophthalmology. Equally, we do not believe that it will be reasonable to justify the application of prior authorisation to the majority of routine, planned elective care or outpatient services provided by the NHS. For example, in the case of orthopaedic or general day surgery, which are routine and form a large number of surgical procedures carried out by the NHS, we do not believe it would be possible, in the majority of cases, to demonstrate through evidence that these services meet the requirements of the criteria in a(i) and (ii) as set out above.

#### *Specialised & high cost services*

- 6.124. Although the majority of NHS services in England are currently commissioned by PCTs, there are different arrangements for commissioning "specialised services". A specialised service is defined as a service which covers a planning population of more than one million people. A "Specialised Services National Definitions Set", has been established to help with the identification of activity that should be regarded as specialised and therefore subject to collaborative commissioning arrangements on a regional or supra-regional basis.



- 6.125. In addition, there is a further list comprising 68 highly specialised services, which are commissioned on a national basis by the National Specialised Commissioning Team based at NHS London. This list is set out in statute<sup>6</sup>. Generally speaking, these are services that affect fewer than 500 people across England and where the evidence suggests that it makes sense (for economies of scale, training etc) to undertake such commissioning at a national level.
- 6.126. As part of the NHS reform programme, the current national list of 68 services set out in statute and the services listed in the “Specialised Services National Definitions Set”, will be consolidated within a set of regulations to be operated by the NHS Commissioning Board from 1 April 2013 (when it takes over the responsibility for specialised commissioning for England). This new consolidated list of services is set out at Annex B.
- 6.127. Applications for cross-border healthcare (and where necessary prior authorisation) will from 1 April 2013 also be handled centrally by the NHS Commissioning Board. Therefore, because these are services that are very costly to provide, require high levels of skill and training, long term investment in infrastructure and medical equipment and often the setting up of dedicated teams, we believe there is a clear symmetry in aligning this consolidated list of specialised services with the categories for prior authorisation.
- 6.128. However, there may be other treatments and interventions, which require significant levels of health system planning or cost-intensive medical infrastructure that may potentially need to be included in the list of categories of "treatments subject to prior authorisation". For example, complex diagnostics and imaging services (MRI etc), which can cost millions of pounds in capital set up costs, training and so on. We welcome views on other such services that might be included in the categories of treatments subject to prior authorisation.

### Consultation questions

- Do you agree that the UK should continue to operate a system of prior authorisation for patients requiring certain types of treatment?
- In addition to specialist services and services such as diagnostics requiring considerable planning and financing what other services might come within the scope of treatments / services that should be subject to prior authorisation?
- What is the evidence to support this inclusion?

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<sup>6</sup> The National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administration Arrangements) (England) (Amendment) Regulations 2012 – S.I. 2012 No.417

*Interaction with Regulation (EC) No 883/2004*

- 6.129. Significantly, Art.8(3) states that when a patient requests prior authorisation for a relevant treatment, the home state must first of all determine whether or not the patient meets the requirements of Regulation 883/2004. If they do, they should be granted authorisation under the Regulation unless the patient specifically requests to use the Directive – for example, to access the private/independent sector abroad.
- 6.130. The NHS Commissioning Board in England will consider the relevant aspects of both the Regulation and Directive routes in the future as part of the responsibilities transferring from PCTs in April 2013. This will ensure that appropriate consideration occurs of patients rights under both sets of legislation and that the relevant case law is applied effectively. This provision will need to be reflected in the implementing regulations and backed by guidance.

*Rare disease*

- 6.131. Finally, Art.8(4) states that if a patient is suspected of having a rare disease and applies for authorisation, the home state *may* carry out a clinical evaluation by experts. If there are no experts for the rare disease in question in the home system, or if the expert's opinion is inconclusive, the home state may request scientific advice of experts in another State. This clause reflects the EU Parliament's and Commission's growing interest in seeking to advance the rights of citizens suffering with rare disease in particular (rare disease is defined as a prevalence of 5:10000). However, this is discretionary and not a binding obligation and as such does not require specific provision in the implementing legislation.

## Article 9 – Administrative procedures regarding cross-border healthcare

- 6.132. This Article requires Member States to have administrative procedures for dealing with cross-border healthcare and reimbursement which are objective and non-discriminatory. The procedures must be made public and must set out reasonable time limits for dealing with requests for authorisation, taking account of the patient's medical condition, urgency and individual circumstances. We propose replicating in the implementing regulations the current legislative provision of 20 working days for the decision making process (unless further information is required). As with current arrangements, decisions on requests must be challengeable, both by administrative review and judicial proceedings.
- 6.133. We propose including in guidance accompanying the implementing regulations a section entitled "general principles", to capture the way in which national authorities should generally approach requests for cross-border healthcare – e.g. applying the

principles of transparency, objectivity, non-discrimination etc. These are important principles upon which judgements would be made in any subsequent challenge.

- 6.134. Article 9 also allows Member States to set up voluntary prior notification schemes, for services which are not subject to mandatory prior authorisation, where the patient can receive confirmation in advance of entitlement and a written estimate of the level of reimbursement they would be due. It also allows Member States to decide to use the existing mechanisms under the Regulation for the payment of costs incurred by patients under the Directive.
- 6.135. We believe there is a benefit for patients to have a dialogue with their local commissioner (or the NHS Commissioning Board) about entitlement and reimbursement levels (and we would encourage patients to do so), but we are aware that any mandatory requirement to do so is likely to be disproportionate and overly bureaucratic. However, there may be some merit in a voluntary system, operated by the NHS Commissioning Board, which encourages the correct dialogue to take place between patient and national authority in advance of treatment not subject to mandatory prior authorisation and we welcome the views of consultees on this.

### Consultation questions

- Is the current decision making timescale reasonable, or should it be amended?
- Would a system of voluntary prior notification for some services not subject to mandatory authorisation be helpful in creating dialogue where cross-border healthcare is being considered?
- What would such a system look like and how could it work in practice?

## Article 10 – Mutual assistance and cooperation

- 6.136. This article needs to be read (and implemented) in conjunction with Articles 4 and 6. It requires Member States to cooperate on the implementation of the Directive, specifically on standards and guidelines on quality and safety, clarification of invoices and the exchange of information - particularly between national contact points. Clarifying bills, providing clear invoices and supporting information is likely to form a significant part of the NCP's responsibilities and is where the role of the NCP will bring potentially significant value.
- 6.137. The Member State of treatment must, on request from the authorities of other Member States make information available about the right of health professionals to practice in their territory. This would require professional regulators to share the registration status

of health professionals when requested through the Commission Internal Market Information (IMI) system. This is now obligatory for this Directive and all competent authorities that would be exchanging such information should be using the IMI system.

6.138. Moreover, while we believe the principles behind this requirement are sound, there are questions to be resolved about what (if any) information is exchanged where a treating practitioner is the subject of an investigation in another Member State, but not at that time charge or disciplinary/court action etc. We welcome the views of respondents to this consultation.

### Consultation question

- What information should be shared between competent authorities on treating practitioners, and in what circumstances?

## Article 11 – Recognition of prescriptions issued in another Member State

6.139. This article requires Member States to accept and dispense prescriptions issued by medical doctors from other Member States. This would mean that, for example, a UK GP could write a prescription that would be dispensed in another EU Member State for continuity of care purposes. However, it does not affect any national rules that states have for prescribing and dispensing - particularly ethical rules, e.g. for the right of pharmacists to refuse to dispense had the prescription been issued in the home system.

6.140. Art.11 also sets out proposals covering issues such as how to identify the medicinal products prescribed and how to verify the identity of the prescriber. Through the formation of two expert groups, the Commission shall adopt:

- Measures on verification and authenticity of prescriptions through developing a non-exhaustive list of elements to be included in the prescription as well as where necessary facilitating contact between prescriber and dispenser;
- Guidelines supporting States on the interoperability of e-prescriptions;
- Measures to facilitate the identification of products or devices and on substitution.
- Measures to facilitate that patients have appropriate information about the prescription including on active substance and dosage.

6.141. These measures will be developed through a committee comprised of the Member States and are to be adopted 20 months after the coming into force of the Directive.

Art.11(4) confirms that the Commission must have regard to the proportionality and cost compliance on Member States of any measures or guidelines brought forward by this work. The Commission must also take measures as to specific products or devices that are to be excluded under the recognition provisions to safeguard public health.

### *Non-exhaustive list of elements to be included in cross-border prescriptions*

- 6.142. The Commission adopted the non-exhaustive list of particulars to be contained in a cross-border prescription in November 2012, following meetings of the expert groups. In terms of the overall policy on medicinal products, this is a Medicines and Healthcare products Regulatory Agency (MHRA) lead and the provisions are governed by the Human Medicines Regulations 2012, which is UK-wide in scope. Under the Regulations, provisions are already in place that provide much of what Art.11 aims to achieve – pharmacists can currently dispense prescriptions written by doctors and dentists lawfully practising medicine or dentistry in another EEA State or Switzerland, provided certain conditions are met. The decision to accept the prescription is subject to the professional judgement of the pharmacist.
- 6.143. The conditions which must be met are that the prescription is signed by the EEA prescriber in ink or, if it is an electronic prescription, signed with an advanced electronic signature. The prescription must also contain the address of the prescriber, an indication of whether he or she is a doctor or dentist and the name of the patient. The new non-exhaustive list (attached at Annex \*\*) sets out more detailed particulars although in practice, many are routinely included in UK prescriptions. As far as outgoing prescriptions from the UK are concerned, these particulars would only apply to a prescription when the patient indicates that they wish to use it in another Member State.
- 6.144. We intend to amend medicines legislation to adopt the non-exhaustive list for both incoming and outgoing cross-border prescriptions. We consider that this will benefit patient safety and offer more certainty for the dispensing pharmacist. Nevertheless, the pharmacist will retain discretion over whether the prescription is accepted or not. No changes will be made to the present arrangements for prescriptions written by UK prescribers for dispensing in the UK.

### *Controlled drugs*

- 6.145. During negotiations on the cross-border Directive it was established that the controlled drugs exclusion under current domestic regulations will come within the scope of medicinal products subject to special medical prescription (SMP) under Art.11(6).
- 6.146. Under European and domestic legislation, unless they are exempted by legislation, medicinal products require a marketing authorisation under which the product is classified as one which is either available only on prescription (POM) or is available without a prescription. Although the relevant governing Directive (2001/83/EC) allows

Member States to designate certain types of SMP products as a sub-category of POM, this designation has never been made in UK legislation because the requirement is not mandatory - and in the Government's opinion, no compelling need to make such a designation was identified.

- 6.147. Upon implementation of the Cross-border Directive, the SMP category of medicines will need to be designated in domestic legislation, as there is no provision in the Directive to deem certain products as if they were SMP products only. In January 2010, the Commission was notified that drugs in Schedules 1 – 3 of the UK Misuse of Drugs Regulations would be designated as SSMP – and therefore remain excluded from EEA prescriptions.
- 6.148. The changes will be implemented by way of an amending SI using the power in section 2(2) of the European Communities Act 1972. In terms of the overall policy on medicinal products, this is a Medicines and Healthcare products Regulatory Agency (MHRA) lead and the provisions are governed by the Medicines Act 1968, as amended, which is UK-wide in scope. Provisions are in place in domestic legislation that provide much of what Art.11 aims to achieve – where they are not, separate implementing legislation will be prepared by the MHRA. The Agency does not envisage that the adoption of the SMP category into UK law will impact on stakeholders as any practical effects will fall on its internal administrative processes.

### Article 12 – European reference networks

- 6.149. This article sets out a mix of Commission responsibilities and provisions to support Member States in the development of EEA-wide reference networks. These would be networks linking healthcare providers and centres of expertise in the Member States, and might work to improve access to diagnosis and the provision of high-quality healthcare to all patients who have conditions requiring a particular concentration of resources or expertise.
- 6.150. Participation is voluntary, albeit expected and encouraged and as with Art.8(4), the Commission's key focus of attention is advancing the agenda on rare disease. Art.12 sets out the criteria for the establishment of a network to include:
- European cooperation on highly specialised healthcare;
  - Contributing to the pool of knowledge on sickness prevention;
  - Facilitate improvements in diagnosis and treatment particularly for patients with rare disease;
  - Maximising the cost-effective use of resources;

- Reinforce research, surveillance and training for health professionals;
- Facilitate the mobility of expertise virtually or physically and spread information and best practice particularly in developments on the diagnosis of rare disease;
- Encourage the development of quality and safety benchmarks to spread best practice;
- Help Member States who lack capacity in the provision of highly specialised services.

6.151. The Commission will develop criteria for establishing networks and facilitate the exchange of information and expertise. In adopting these measures, the Commission will do so through a committee comprised of the Member States under the delegated acts powers. Measures under this article are not intended to harmonise Member States' health systems and cannot be forced on Member States who do not participate.

6.152. In terms of Directive implementation, no implementing legislation is required in this area. Whatever results from the work of the voluntary network is not a result of the legal obligation to transpose Directive requirements, but of separate decisions taken by the UK to participate in future work in this area (which will go through its own development and assessment process).

### Article 13 – Rare diseases

6.153. Article 13 was a late addition to the Directive to strengthen the message on pan-European cooperation and treatment of rare disease. There are no immediate legislative requirements arising from this article but it does serve as a clear signpost as to the Commission's future interest.

### Article 14 – eHealth

6.154. Article 14 is intended to support and facilitate cooperation and the exchange of information among Member States, working within a voluntary network on the eHealth agenda for the transmission of data in cross-border care. Article 14 sets out that the objectives of the network will be:

- To work towards interoperability of e-Health systems and services;
- To draw up guidelines on patient summaries' data to be shared across borders;
- effective methods for enabling the use of medical information for public health and research;

- developing common identification and authentication measures to facilitate cross-border healthcare

- 6.155. The Commission has established a committee comprised of the Member States for the set up and functioning of the network. All Member States, including the UK, were represented at the first meeting of the voluntary network on the 8 May 2012 in Copenhagen. Measures adopted shall not interfere with Member States' competence in implementing eHealth systems or harmonise national laws so are not mandatory.
- 6.156. In terms of Directive implementation, no implementing legislation is required in this area. Whatever results from the work of the voluntary network is not a result of the legal obligation to transpose Directive requirements, but of separate decisions taken by the UK to participate in future work in this area (which will go through its own development and assessment process).

### Article 15 – Cooperation on health technology assessment

- 6.157. Article 15 provides for the Commission to set up and support a voluntary network in the area of health technology assessment (HTA). This aims to build on several years' cooperation in HTA at EU level through a series of EU-funded projects and, most recently, the Joint Action on Health Technology Assessment 'EUnetHTA' (more information about EUnetHTA can be accessed through the website: [www.eunetha.eu](http://www.eunetha.eu)). Two UK partners are active participants in this work, the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) and the National Institute for Health and Clinical Excellence (NICE).
- 6.158. The UK supports international collaboration in HTA and welcomes the Commission's support for ongoing voluntary cooperation in this area. However, decisions about which treatments to provide, including the assessment of new medicines and technologies, clearly form part of Member State's responsibilities in the organisation, financing and management of national health systems. Different systems use health technology assessment in different ways and EU initiatives in this area, including the voluntary network, must in our view reflect this. In particular, it is important to be clear that we are not working towards the creation of a single EU HTA body.
- 6.159. We believe that sharing of information and methods, and streamlining of information requirements are likely to be the most valuable and productive areas for continuing cooperation in HTA at EU level. DH looks forward to being fully involved in the development of the voluntary European network on HTA. The Commission will adopt measures for the establishment of the network and the arrangements for granting aid by setting up a committee of Member States. These measures are not mandatory and will not form part of the Directive implementing legislation.



6.160. The Commission has recently conducted a public consultation on "Modalities of stakeholder consultation in the voluntary Health Technology Assessment network to be established under Directive 2011/24/EU". Information about this consultation, which closed on 1 August 2012, is available from the European Commission's website at:

[http://ec.europa.eu/health/technology\\_assessment/consultations/cons\\_hta\\_network\\_en.htm](http://ec.europa.eu/health/technology_assessment/consultations/cons_hta_network_en.htm)

### Consultation questions

- How do you think the European reference networks and proposed ehealth and health technology assessment networks might best add value to the UK?
- What impact might these have on current UK systems?

## Articles 16-19 - Committee & delegated acts

6.161. Much of the detail in these articles is about Commission procedures. They deal with the powers of the Commission to set up the committees for the cooperation measures set out in Articles 10-15 of the Directive. They also set out the powers of the European Parliament or Council of Ministers to revoke the delegated powers of the Commission (Article 17) or to object to the powers proposed (Article 18). There is nothing in articles 16-19 that requires implementation into UK law.

## Article 20 – Reports

6.162. Article 20 requires the Commission to compile a report on the operation of the Directive, two years from the date of transposition – i.e. by 25 October 2015 - and then every three years thereafter.

6.163. There are specific requirements for the Commission to report on Member States' use of the provisions on limiting the application on rules on reimbursement for reasons of general interest (Article 7(9)), on prior authorisation (Article 8) and on the functioning of National Contact Points and European Reference Networks and (Articles 6 and 12 respectively). There are also provisions for Member States to resolve any financial issues in respect of Regulation 883/2004 resulting from Article 7 of the Directive.

6.164. To implement Article 20, there is an additional requirement on Member States to provide the Commission with "...assistance and all information for carrying out the assessment and preparing the reports", which we anticipate will need to be built in to the responsibilities of the National Contact Point(s) (Art.6) and national authorities. We

understand that the European Commission intends specifying a range of data and information requirements about the uptake and use of the Directive, which Member States will be asked to collect.

- 6.165. In England, this may be a job that the NHS Commissioning Board leads or at the very least inputs to, so we will need to use a direction under the Health & Social Care Act to direct the Board in its responsibilities.

### Article 21 – Transposition

- 6.166. This requires Member States to transpose (implement) the Directive into their national laws within 30 months of the Directive coming into force – i.e. by 25 October 2013. The intention is that the legislation required to implement the Directive will come into force on the 25 October 2013.

## 7. Annexes

### Annex A

#### The Health Regulators and Professions Regulated

Health professional regulator	Regulated health profession
General Chiropractic Council	Chiropractors
General Dental Council	Dentists Dental hygienists Dental therapists Clinical dental technicians Orthodontic therapists Dental nurses Dental technicians
General Medical Council	Doctors
General Optical Council	Dispensing opticians Optometrists
General Osteopathic Council	Osteopaths
General Pharmaceutical Council	Pharmacists Pharmacy technicians
Health Professions Council	Arts therapists Biomedical scientists Chiropodists Clinical scientists Dieticians Hearing aid dispensers Occupational therapists Operating department practitioners Orthoptists Orthotists Paramedics Physiotherapists Podiatrists Practitioner psychologists Prosthetists Radiographers Speech and language therapists
Nursing and Midwifery Council	Nurses Midwives
Pharmaceutical Society of Northern Ireland	Pharmacists

**Specialised Commissioning:  
Services for Rare & Very Rare Diseases  
(Schedule 4 of the NHS Commissioning Board and Clinical Commissioning Groups  
(Responsibilities and Standing Rules) Regulations 2012**

Adult ataxia telangiectasia services.  
Adult congenital heart disease services.  
Adult highly specialist pain management services.  
Adult highly specialist respiratory services.  
Adult highly specialist rheumatology services.  
Adult secure mental health services.  
Adult specialist cardiac services.  
Adult specialist eating disorder services.  
Adult specialist endocrinology services.  
Adult specialist intestinal failure services.  
Adult specialist neurosciences services.  
Adult specialist ophthalmology services.  
Adult specialist orthopaedic services.  
Adult specialist pulmonary hypertension services.  
Adult specialist renal services.  
Adult specialist services for patients infected with HIV.  
Adult specialist vascular services.  
Adult thoracic surgery services.  
Alkaptonuria service.  
Alström syndrome service.  
Ataxia telangiectasia service for children.  
Autoimmune paediatric gut syndromes service.  
Autologous intestinal reconstruction service for adults.  
Bardet-Biedl syndrome service.  
Barth syndrome service.  
Beckwith-Wiedemann syndrome with macroglossia service.  
Behcet's syndrome service.  
Bladder exstrophy service.  
Blood and marrow transplantation services.  
Bone anchored hearing aid services.  
Breast radiotherapy injury rehabilitation service.  
Child and adolescent mental health services – Tier 4.  
Choriocarcinoma service.  
Chronic pulmonary aspergillosis service.  
Cleft lip and palate services.  
Cochlear implantation services.  
Complex childhood osteogenesis imperfecta service.  
Complex Ehlers Danlos syndrome service.  
Complex neurofibromatosis type 1 service.  
Complex spinal surgery services.  
Complex tracheal disease service.  
Congenital hyperinsulinism service.  
Craniofacial service.  
Cryopyrin associated periodic syndrome service.  
Cystic fibrosis services.  
Diagnostic service for amyloidosis.  
Diagnostic service for primary ciliary dyskinesia.  
Diagnostic service for rare neuromuscular disorders.

## Cross Border Healthcare & Patient Mobility

Encapsulating peritoneal sclerosis treatment service.  
Epidermolysis bullosa service.  
Extra corporeal membrane oxygenation service for adults.  
Extra corporeal membrane oxygenation service for neonates, infants and children with respiratory failure.  
Ex-vivo partial nephrectomy service.  
Fetal medicine services.  
Gender identity development service for children and adolescents.  
Gender identity disorder services.  
Heart and lung transplantation service (including bridge to transplant using mechanical circulatory support).  
Highly specialist adult urinary and gynaecological surgery services.  
Highly specialist allergy services.  
Highly specialist colorectal surgery services.  
Highly specialist dermatology services.  
Highly specialist metabolic disorder services.  
Highly specialist pain management services for children and young people.  
Highly specialist palliative care services for children and young people.  
Highly specialist services for adults with infectious diseases.  
Hyperbaric oxygen treatment services.  
Insulin-resistant diabetes service.  
Islet transplantation service.  
Liver transplantation service.  
Lymphangiomyomatosis service.  
Lysosomal storage disorder service.  
Major trauma services.  
McArdle's disease service.  
Mental health service for deaf children and adolescents.  
Middle ear implantable hearing aid services.  
Neurofibromatosis type 2 service.  
Neuromyelitis optica service.  
Neuropsychiatry services.  
Ocular oncology service.  
Ophthalmic pathology service.  
Osteo-odonto-keratoprosthesis service for corneal blindness.  
Paediatric and perinatal post mortem services.  
Paediatric cardiac services.  
Paediatric intestinal pseudo-obstructive disorders service.  
Pancreas transplantation service.  
Paroxysmal nocturnal haemoglobinuria service.  
Positron Emission Tomography – Computed Tomography services.  
Primary ciliary dyskinesia management service.  
Primary malignant bone tumours service.  
Proton beam therapy service.  
Pseudomyxoma peritonei service.  
Pulmonary hypertension service for children.  
Pulmonary thromboendarterectomy service.  
Radiotherapy services.  
Rare mitochondrial disorders service.  
Reconstructive surgery service for adolescents with congenital malformation of the female genital tract.  
Retinoblastoma service.  
Secure forensic mental health service for young people.  
Severe acute porphyria service.  
Severe combined immunodeficiency and related disorders service.  
Severe intestinal failure service.  
Severe obsessive compulsive disorder and body dysmorphic disorder service.  
Small bowel transplantation service.

## Cross Border Healthcare & Patient Mobility

Specialist burn care services.  
Specialist cancer services.  
Specialist cancer services for children and young people.  
Specialist dentistry services for children and young people.  
Specialist ear, nose and throat services for children and young people.  
Specialist endocrinology and diabetes services for children and young people.  
Specialist gastroenterology, hepatology and nutritional support services for children and young people.  
Specialist genetic services.  
Specialist gynaecology services for children and young people.  
Specialist haematology services for children and young people.  
Specialist haemoglobinopathy services.  
Specialist immunology services for patients with deficient immune systems.  
Specialist mental health services for deaf adults.  
Specialist morbid obesity services.  
Specialist neonatal care services.  
Specialist neuroscience services for children and young people.  
Specialist ophthalmology services for children and young people.  
Specialist orthopaedic surgery services for children and young people.  
Specialist paediatric intensive care services.  
Specialist paediatric liver disease service.  
Specialist perinatal mental health services.  
Specialist plastic surgery services for children and young people.  
Specialist rehabilitation services for patients with highly complex needs.  
Specialist renal services for children and young people.  
Specialist respiratory services for children and young people.  
Specialist rheumatology services for children and young people.  
Specialist services for children and young people with infectious diseases.  
Specialist services for complex liver, biliary and pancreatic diseases in adults.  
Specialist services for haemophilia and other related bleeding disorders.  
Specialist services for severe personality disorder in adults.  
Specialist services to support patients with complex physical disabilities.  
Specialist surgery for children and young people.  
Specialist urology services for children and young people.  
Spinal cord injury services.  
Stem cell transplantation service for juvenile idiopathic arthritis and related connective tissue disorders.  
Stickler syndrome diagnostic service.  
Vein of Galen malformation service.  
Veterans' post traumatic stress disorder programme.  
Wolfram syndrome service.  
Xeroderma pigmentosum service.

## **Non-exhaustive list of elements to be included in medical prescriptions**

*(Headings appearing in bold in this Annex are not required to feature in prescriptions)*

### **Identification of the patient**

- Surname(s);
- First name(s) (written out in full, i.e. no initials);
- Date of Birth.

### **Authentication of the prescription**

- Issue date.

### **Identification of the prescribing health professional**

- Surname(s);
- First name(s) (written out in full, i.e. no initials);
- Professional qualification;
- Details for direct contact (email and telephone or fax, the latter both with international prefix);
- Work address (including the name of the relevant Member State);
- Signature (written or digital, depending on the medium chosen for issuing the prescription).

### **Identification of the prescribed product, where applicable**

- Common name as defined by Article 1 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use;
- The brand name if:
  - (a) the prescribed product is a biological medicinal product or
  - (b) the prescribing health professional deems it medically necessary; in that case, the prescription shall shortly state the reasons justifying the use of the brand name;
- Pharmaceutical formulation (tablet, solution, etc.);
- Quantity;
- Strength, as defined in Article 1 of Directive 2001/83/EC;
- Dosage regimen.

## 8. Summary of questions for stakeholders

### **General**

1. What proportionate measures can we take so that all patients/citizens, regardless of age, race or ethnicity, disability, religion or belief, gender, sexual orientation or socio-economic status feel a) reassured they will be treated with respect and their specific needs considered b) they are fully informed to make the right choice for them?
2. To what extent do you think that these proposals will have a positive or an adverse impact on equity? What can be done to manage any adverse impact?
3. Please provide any evidence you may have on the reasons for which patients travel abroad to receive healthcare, the likely uptake (current and future) of cross-border healthcare by NHS patients as well as the impacts this has on the NHS (budget, administrative costs, commissioning etc).

### **Responsibilities of Member State of treatment (pages 13 - 22)**

4. Are there any other "health professions" in the UK to which the provisions of the Directive will apply when treatment is supplied in the UK?

### **Responsibilities of Member State of affiliation (pages 22 - 26)**

5. Do you agree that this broad requirement would ensure that the NHS is able to deliver the required clarity on entitlements and thereby respond appropriately to patient requests?

### **National Contact Points (pages 26 - 27)**

6. Do you agree that the Commissioning Board is best placed to deliver the NCP function for England?
7. What information, and presented in what format(s), do you think patients need to make an informed decision on receiving treatment in another EU Member State?
8. What will be the impact of providing clear and transparent information on the volume of patients who may wish to access cross-border healthcare and the treatments they may wish to obtain? Please provide evidence where possible.

### **General principles for reimbursement of costs (pages 28 - 33)**

9. Do you agree that the NHS Commissioning Board should have discretion to make payments direct to overseas providers, where this would be beneficial for patients with limited financial means?
10. If so, what safeguards would you like to see put in place?
11. How might any adverse impact be managed?



***Healthcare that may be subject to prior authorisation (pages 33 - 42)***

12. Do you agree that the UK should continue to operate a system of prior authorisation for patients requiring certain types of treatment?

13. In addition to specialist services and services such as diagnostics requiring considerable planning and financing what other services might come within the scope of treatments / services that should be subject to prior authorisation?

14. What is the evidence to support this inclusion?

15. Do you have a view on whether or how the Government should adopt the derogation Art.8(6)(d) derogation?

16. Should the derogation (if taken) be limited to the list of highly specialised services only?

17. Do you believe this Article can be made to work in practice without being unduly burdensome?

***Administrative procedures (pages 42 - 43)***

18. Is the current decision making timescale reasonable, or should it be amended?

19. Would a system of voluntary prior notification for some services not subject to mandatory authorisation be helpful in creating dialogue where cross-border healthcare is being considered?

20. What would such a system look like and how could it work in practice?

***Mutual assistance and cooperation (pages 43 - 48)***

21. What information should be shared between competent authorities on treating practitioners, and in what circumstances?

22. How do you think the European reference networks and proposed ehealth and health technology assessment networks might best add value to the UK?

23. What impact might these have on current UK systems?

## 9. How to respond

Responses on this consultation and the associated documents should, wherever possible be sent by email to [eucross-borderhealthcare@dh.gsi.gov.uk](mailto:eucross-borderhealthcare@dh.gsi.gov.uk) by **24 May 2013**.

Alternatively, responses may be sent by post to:

Rob Dickman  
Room 318, Wellington House  
133-155 Waterloo Road  
London SE1 8UG

### *Any other comments*

While it would be helpful for responses to focus on the questions set out in the document, we would also like to hear any other comments respondents think are relevant to the issues raised by the consultation. In particular, we would be grateful if you could provide us with any evidence, quantitative or qualitative, which you deem relevant and which we have missed in this Consultation Document and the accompanying Impact Assessment.

### *Confidentiality of information*

Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, among other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department. The Department will process your personal data in accordance with the DPA and in most circumstances, this will mean that your personal data will not be disclosed to third parties.

### *Comments on the consultation process itself*

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact: **(Please do not send consultation responses to this address)**

Consultations Co-ordinator  
Department of Health  
3E58 Quarry House  
Leeds LS2 7UE  
Email: [consultations.co-ordinator@dh.gsi.gov.uk](mailto:consultations.co-ordinator@dh.gsi.gov.uk)