

Cross Border Healthcare & Patient Mobility

Public Consultation on Scotland's Transposition and Implementation of Directive 2011/24 EU on the Application of Patients' Rights in Cross-border Healthcare

Responses are invited by Friday 14 June 2013

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Electronic publication and additional copies:

This consultation paper is available via the internet at:

<http://www.scotland.gov.uk/Consultations/Current>

You can use this link to find out more about the consultation.

Or if you want paper copies of the consultation paper, or if you or someone you care for requires the consultation paper in a different format or language, please contact us at:

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Copies of the documents mentioned in this paper can also be obtained from these addresses.

This consultation is being conducted in line with the Scottish Government's consultation process Consultation: Good Practice Guidance¹

This consultation, and all other Scottish Government consultation exercises, can be viewed online on the consultation web pages at <http://www.scotland.gov.uk/consultations>. You can telephone Freephone 0800 77 1234 to find out where your nearest public internet access point is. There will be no charge for this call.

¹<http://www.scotland.gov.uk/Resource/Doc/1066/0006061.pdf>

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Directive 2011/24 EU on the application of patients' rights in cross-border healthcare

Purpose of the consultation

1.1 This consultation document sets out the Scottish Government's approach to implementation of the EU Directive on the application of patients' rights in cross-border healthcare. It seeks views on the detail of the implementation, and examines the effects the Directive may have on Scotland's health system.

1.2 The Directive clarifies citizens' rights to access healthcare in another Member State of the European Economic Area (EEA)², sets out the grounds on which they can claim reimbursement of the eligible costs of treatment from their home healthcare system. The Directive also sets out a number of areas for EU-wide co-operation in healthcare.

1.3 The purpose of the Directive is not to foster or promote cross-border healthcare, but to facilitate access to healthcare services in other Member States 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 Scottish Government's overall approach to implementation, as well as how it proposes to meet the individual obligations contained in the Directive.

² The Member States of the European Union plus Iceland, Liechtenstein and Norway

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 certain instances, it may benefit the patient to obtain healthcare in another European country, where there may be better expertise available, lower costs, more availability of certain highly specialised treatments or where waiting times are shorter.

2.2 EU regulations on the co-ordination 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 to another country.

2.4 Over the last fifteen years, there have been more than a dozen high profile legal challenges in which Member States' interpretation of the rules in respect of obtaining healthcare across borders has been questioned and the European Court of Justice (ECJ) has been called upon to make a determination. The development of this case-law based on individual cases (including a case in 2006 against the UK in the case of *Yvonne Watts -v- Bedford PCT*³, 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 judgments being made in the courts, based on health systems which are very different in organization 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 existing rights under the Treaties and 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.

³ 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")

2.6 The Directive's 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 co-operation between Member States.

2.7 The Directive sets out the information Member States must provide for citizens from other states considering coming to the country to purchase healthcare. It also sets out the arrangements that a Member State must provide to allow its own citizens to establish the extent of their right to reimbursement of the costs of cross-border healthcare if they choose to seek healthcare in another Member State. 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.

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

2.9 **The Directive can be viewed or downloaded at:**

[The Directive of the European Commission and of the Council on the Application of Patients' Rights in Cross-border Healthcare](#)

Previous consultations & reference material

The European Commission's original proposal for a Directive

3.1 The Scottish Government consulted on the first draft of the Directive when it was published in July 2008. This 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 and responses to it are available to download from the Scottish Government's website via the following link:

<http://www.scotland.gov.uk/Consultations/Closed/Q/page/19>

2010 Interim Regulations

3.3 In 2010 the Scottish Government sought views from within the NHS in Scotland 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 (now Article 56) of the Treaty. It then introduced interim Reimbursement Regulations, which came into force in July 2010, and supporting guidance CEL (2010) 30, which can be downloaded at:

<http://www.show.scot.nhs.uk/publications/publication.asp?name=&org=&keyword=cross-border&category=6&number=10&sort=tDate&order=DESC&Submit=Go>

The Administrations That Make Up the UK

3.4 Health is a devolved matter and Health Departments in England, Wales, Northern Ireland and Gibraltar⁴ will be using their own consultation and other legislative processes to seek views on the Directive in their respective countries. However, each of the Health Departments must work closely to arrive at consistent positions, as far as this can be achieved.

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

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Implementation of Directive 2011/24 EU

Summary

4.1 The Directive seeks to clarify the numerous case law precedents that have been established over a number of years by the ECJ, 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.

4.2 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 legislation as necessary. Where the EU legislation has not been effectively implemented, Member States may risk legal action and corresponding financial penalties (known as "infraction" proceedings).

4.3 This is a broad based and complex Directive. It covers all aspects of healthcare (but not long-term care which provides assistance with routine everyday tasks – i.e. social care).

What is needed?

4.4 A set of Scottish regulations is required to implement the main provisions of Directive 2011/24/EU in Scotland. The regulations will need to be made in the summer, to come into force on the transposition deadline. This will allow our NHS system to prepare for the changes that will come into effect on 25 October 2013.

4.5 The implementing regulations will not deal with the requirement for indemnity insurance or similar such arrangements in Article 4 of the Directive, nor the Article 11 requirements around designation of special medical prescriptions and the non-exhaustive list of elements to be presented on prescription forms. These elements will be delivered through separate implementation legislation which is being led by the Department of Health on a UK-wide basis. It is not part of this consultation.

Article by article discussion

Article 1 - Subject matter and scope

5.1 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).

5.2 The Directive covers treatment for long-term medical conditions (e.g. for dialysis, epilepsy etc.), which are within the 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 European Union provisions

6.1 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

7.1 Article 3 defines the terms used in the Directive. In preparing the Regulations to implement the Directive, we will use these definitions where appropriate. However, in some instances where there is existing domestic legislation we will use the appropriate language from that legislation.

7.2 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”). We will aim to make definitions as clear as possible for use within the NHS and by patients.

Article 4 - Responsibilities of the Member State of treatment

8.1 Article 4 sets out the responsibilities of Member States where healthcare providers in their territory are providing treatment under the Directive. The Regulations will deal with visiting patients, that is patients who are insured for healthcare in another Member State and are seeking healthcare in Scotland under the provisions of the Directive. In this scenario, as a part of the Member State, Scotland would be 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 a non-discriminatory manner;

- Ensure transparent complaints procedures and procedures to obtain redress;
- Apply adequate systems of professional liability insurance or similar;
- Respect privacy in processing personal information;
- Supply patients with a copy of the record of their medical treatment.

8.2 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

8.3 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.

8.4 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.

8.5 The definition of “healthcare professional” in the Directive is a doctor of medicine, a nurse, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC or another professional carrying out 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.

8.6 Therefore, in accordance with our national legislation that regulates health professionals, the requirements on “healthcare providers” will apply to “healthcare” provided in Scotland 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 Pharmaceutical Council*
- General Osteopathic Council
- Health and Care Professions Council* (also regulates social workers in England)
- Nursing and Midwifery Council

*The regulation of healthcare professionals is reserved to Westminster apart from certain professional groups regulated by the three bodies highlighted above, where regulation began after the introduction of the Scotland Act 1998. In addition, the regulation of any new professional group by any of the regulatory bodies above or the establishment of a new regulatory body will also be a devolved matter.

Consultation question

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

Obligations on providers

8.7 The focus of Article 4 then moves to how to ensure that the Article 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 statutory healthcare regulators, together with existing consumer protection provisions and that it is not necessary to make further provision in the regulations to implement the Directive.

8.8 The purpose of health profession regulation is to protect the public. Regulation ensures that those who practice a health profession are doing so safely. Regulatory bodies have four main functions:

- Establishing standards of competence, ethics and conduct;
- Establishing Standards of 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. placing conditions on their registration or removing them from the register).

8.9 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 regulated professionals. As such, health professionals are bound to comply with the provisions contained in these documents. Failure to do so brings into question their conduct or performance and then the regulatory bodies can take account of whether the standards have been met, when deciding if it would be appropriate to take "fitness to practice" action to protect the public.

Thus, we believe that a good standard of regulatory coverage is in place for cross-border patients seeking healthcare services in Scotland.

Delivering the Article 4 obligations

National Contact Points - Article 4(2)(a)

8.10 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.

8.11 What is “Relevant information” is not defined, 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 information and access to services. To a large extent, this is an area where Member States will need to co-ordinate their approach, since a degree of uniformity of provision and practice across the Community will be required. Discussions at European level are continuing in this area.

8.12 Our preferred approach to implementation is to re-order the provisions relating to the NCP, which are contained in Articles 4, 6 and 10 of the Directive and to group them together in the domestic Regulations (see also the discussion around Article 6 below). We would then provide detailed guidance on “how” the NCP will go about its business.

Pricing & how much to charge patients - Article 4(2)(b) & (4)

8.13 The Directive requires healthcare providers to give patients clear information on prices and to provide them with clear invoices. Providers cannot seek to charge more simply because the person is an EEA patient seeking treatment under the Directive.

8.14 In terms of how these requirements are met, for secondary NHS care, NHS Boards should recover the full cost of the treatment provided to EEA patient under the Directive, including 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.

8.15 A number of methods for charging exist in primary care, where services are provided by GP practices, dental practices and community pharmacies and high street optometrists. There is no formal tariff system in primary care, so the current system of patient charging will depend on the treatment or service that is required.

8.16 For GP and out of hour services, if an EEA national is treated as an NHS patient (as they should be unless they specifically ask to be treated

privately), then the treatment / consultation is free of charge. However, while NHS prescriptions are free to patients who are ordinarily resident in Scotland, EEA patients should be charged the actual NHS tariff cost of any medication that is dispensed by a community pharmacist.

8.17 While NHS dental patients who are ordinarily resident in Scotland pay 80% of the cost of NHS dental treatment, up to a ceiling of £384, EEA patients should be charged the actual cost of NHS dental treatment with no dispensations.

8.18 Some groups of patients who are ordinarily resident in Scotland are entitled to free NHS sight tests and optical vouchers to help with spectacles or contact lenses. The same principles should be applied in calculating charges for EEA patients.

Independent Providers

8.19 An EEA patient seeking treatment in Scotland may 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 healthcare provided to a visiting patient by either the public (NHS) or private sector. However, Member States are not obliged to provide more extensive information on accessing private healthcare to visiting patients than it provides for its own resident patients.

8.20 We consider that the obligation on clear information on prices and invoices can be satisfied by domestic consumer protection legislation - in particular, the Consumer Protection from Unfair Trading Regulations 2008. This legislation sets 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. 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

8.21 Article 4 requires non-discrimination with regard to nationality; in particular, Article 4(2) requires the Member State providing the treatment to ensure that an incoming patient is charged the same prices that apply to a domestic patient in a compatible 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 (Article 4(4)).

8.22 This also means that independent providers who deliver NHS services will only be able to charge the same price as that for resident NHS patients, should an EEA patient seek treatment as if they were an NHS patient. They will only be able to charge the patient on a private basis if the patient has specifically asked to be treated privately.

8.23 Providers cannot routinely refuse EEA patients 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 patients who are not ordinarily resident in Scotland.

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

Transparent complaints procedures - Article 4(2)(c)

8.25 Details of the Scottish NHS Complaints Procedure are available through the Health Rights Information Scotland Website at:

<http://www.hris.org.uk/index.aspx?o=1025>

Professional liability insurance - Article 4(2)(d)

8.26 Article 4(2)(d) sets out the requirements for systems of professional liability insurance (or similar such arrangement). This means that any healthcare 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 UK and Scottish 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 - Article 4(2)(e)&(f)

8.27 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, granting 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).

8.28 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.

8.29 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. A health record can be recorded in computerised or manual form or in a mixture of both.

8.30 A health record 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.scotland.gov.uk/Publications/2012/01/10143104/0>

<http://www.hris.org.uk/index.aspx?o=1026>

Other General Principles

8.31 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. Article 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 appropriate. 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.

8.32 Member States may provide information in other EU languages if they choose to do so. We propose covering all of these points in guidance.

Article 5 - Responsibilities of the Member State of affiliation

9.1 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.

9.2 Information about providers or services available in other Member States may also be facilitated through the respective National Contact Points. As such, Article 5 is central in making the Directive workable and relevant for EU citizens.

9.3 The Directive sets out 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 at home to the patient in Scotland under the NHS. Importantly it is not about the NHS formally commissioning healthcare for patients in other EEA Member State. Separate rules exist to regulate this. For example when healthcare providers decide that a rare cancer should receive proton beam therapy, as this technology is not available on the NHS at this time.

9.4 In choosing to access healthcare in another Member State, the home patient is effectively stepping outside the NHS system and using their rights under EU law to seek healthcare elsewhere in the EEA.

9.5 At this point, the patient is taking individual responsibility for ensuring that the treatment they obtain is appropriate and safe within the laws of the country of treatment (not under UK or Scottish legislation). The NHS in Scotland will not be commissioning treatment or services from foreign providers under Article 5 and will not be responsible or liable in any way for the outcome of treatment provided. The implementing regulations will, however, need to impose the duties set out in Article 5 on relevant NHS bodies such as NHS Boards and the National Contact Point.

Publicising information on rights

9.6 In terms of making information on rights and entitlements publicly available, we will need to consider what communication channels we use for Scottish citizens. At the moment we package Regulation 883/2004 and the Directive together in a section on Healthcare in Europe on the Scottish Government web site at:

<http://www.scotland.gov.uk/Topics/Health/Services/Europe/Healthcare-Directive>

9.7 This will be revised to take account of the implementation of the Directive and to give greater emphasis on individual rights and the processes that are in place. The NCP and NHS Boards will also have a strong online presence from which information on the procedures and processes to follow can be publicised. We will also work with NHS Boards to develop approaches to reach GPs and other general medical services providers within a comprehensive information and engagement strategy to ensure that all parts of the health system in Scotland respond effectively and appropriately to patient requests.

Issues

9.8 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 by the NHS in terms of treatment policies, criteria and thresholds for treatment. However, much of this information is not accessible to patients and needs to be made available in easily understood formats.

9.9 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.

9.10 However, the way in which European law continues to develop suggests that countries that 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.

9.11 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.

9.12 To avoid the risk of challenge in the future, the NHS will now need to provide patients with much greater levels of clarity as to which services the NHS does and does not in principle fund. If information on entitlements is not publicised and patients challenge the NHS on the basis that they had no means of knowing that 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, healthcare providers 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.**

9.13 In transposing the Directive, the Scottish Government will seek to set out the principles under which the NHS should provide clarity on entitlements to patients. There is also a need to assess the adequacy and consistency of current system requirements, and whether these leave the NHS in Scotland vulnerable to challenge on the administrative processes that patients have to go through to get information on the availability of particular treatments.

9.14 In setting out the principles under which the NHS should provide clarity on entitlements to patients in the implementing regulations, we propose placing a broad legal requirement on NHS Boards to provide information to patients on their rights and entitlements in relation to receiving cross-border healthcare. The regulatory measure would set the basic legal framework for health commissioners (NHS Boards) and detailed underpinning guidance would set out how the requirements are to be met, including:

- the information to be provided (this would need to include published information on services that are not generally available to NHS patients, including clinical and other access thresholds);
- how the information will be provided;
- the time limits by which it should be made available;
- training requirements for staff dealing with queries; and
- any other necessary directions to ensure this this function is delivered appropriately.

9.15 In the information they publish for patients, NHS Boards 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).

9.16 Where NHS Boards 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 there is not a policy in place, we would not seek to require Boards to develop new policies about services they do or do not commission. But by the same token patients cannot be made to wait for weeks while a policy is developed and agreed locally.

9.17 It is proposed that NHS Boards and / or the National Contact Point will act as contact points for patients wishing to ascertain whether or not a treatment is available and whether or not there is a policy or published information on the availability of the treatment sought. Guidance will cover what is specifically required, and we propose to ensure that, from the outset, patients can get the information they need easily without requiring NHS Boards to do more than is necessary to ensure that this is achieved.

Consultation questions

- **Do you agree that this broad requirement would ensure that NHS Scotland is able to deliver the required clarity on entitlements and thereby respond appropriately to requests from patients for information on their entitlements?**
- **If not, what additional measures should be considered to ensure that NHS Scotland is able to deliver the required clarity on entitlements and thereby respond appropriately to patients' requests?**

Article 6 - National Contact Points for cross-border healthcare

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

- provide information including right of specific healthcare provider to provide services and any restriction on its practice;
- provide information about patient 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 Regulation 883/2004 (the S2 scheme) 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; and
- co-operate with other NCPs and the Commission and provide patients with contact details of NCPs in other Member States.

10.2 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 and expectations of the Equality Act 2010 (which is UK-wide in scope and contains specific provision for reasonable adjustments to be made by public bodies in respect of disabled persons).

10.3 Scotland will set in place its own NCP arrangements as will England, Wales, Northern Ireland and Gibraltar. The five NCPs will need to link together for the UK as a whole.

10.4 NHS 24, through its health information service (branded as NHS Inform) is the most appropriate existing NHS body to assume the role of NCP for Scotland as its function is to provide an extensive range of health and health-related information to the public.

10.5 The NCP for Scotland will need to be formally established via the implementing legislation. 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. The legislation that constitutes NHS 24 will also need to be amended to reflect its enhanced role.

Consultation questions

- **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 will be the impact of providing clear and transparent information on the likely volume of patients who may wish to access cross-border healthcare?**

Article 7 - General principles for reimbursement of costs

11.1 Article 7 requires the patient's home Member State to reimburse the cost of cross-border healthcare, subject to the derogation in Article 7(2), which deals with healthcare provided under Regulation 883/2004.

11.2 Article 7(2)(a) does not apply to the UK. The derogation at Article 7(2) 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 a UK state retirement pension who has retired to another Member State to live.

11.3 Broadly, when such a person returns to the Competent Member State for a visit, then any healthcare obtained during the visit, that 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 or any long-term contribution-based social security allowance such as Incapacity Benefit.

11.4 Returning to the 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 services would have been made available to the patient by the home state healthcare System. 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.

11.5 However, 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.

11.6 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. Nevertheless, under Article 7(6) Member States must also have a transparent mechanism in place 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.

11.7 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.

11.8 Scotland would need to be able to show that such a restriction was proportionate and not discriminatory. Given the requirements for Member States to collect information under other parts of the Directive, it is likely that any damaging high level of demand would become apparent relatively quickly.

What to reimburse

11.9 The current mechanisms for reimbursing patients in Scotland are operated at local level by NHS Boards. 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.

11.10 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 health authorities to be able to explain the reimbursement calculation and be able to justify it to applicants.

11.11 Reimbursement of primary care treatments and services will need to take account of the different arrangements that apply to different services.

Calculating reimbursable costs

11.12 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 are 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).

11.13 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.

Equity

11.14 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 those without the necessary financial resources from accessing cross-border treatment.

11.15 For this reason, and building on the existing discretion of NHS Boards, we believe it would be appropriate for the Boards to have the discretion 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. However, it is imperative in allowing this that we do not invoke the NHS duty of care, as the NHS Boards will never be formally commissioning

the treatment - they will simply be assisting the patient in exercising his or her individual rights.

11.16 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 NHS Boards for use where patients would otherwise struggle to meet the cost of treatment in advance, because of 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 with the relevant NHS Board acting as a third party and being in no way liable for the outcome of treatment.

Consultation questions

- **Do you agree that NHS Boards should be able 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?**
- **To what extent do you think these proposals will have a positive or an adverse impact?**

11.17 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.

11.18 We have 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

12.1 Article 8 (1) allows Member States to operate a system of prior authorisation for healthcare that satisfies the criteria set out in Article 8(2). As derogation from the primary purpose of the Directive, the way in which a system of prior authorisation is operated will be interpreted by the courts. Any system of prior authorisation and decisions to grant or refuse

authorisation is restricted to what is necessary and appropriate. A blanket approach cannot be adopted, nor can a system of prior authorisation be used to discriminate against patients or place obstacles in the way of their rights under the Directive.

12.2 Currently, in Scotland, patients seeking treatment in another EEA Member State should contact their GP or local NHS Board in advance of travelling to discuss whether prior authorisation is required and what levels of cost reimbursement will apply. This should happen before the patient accesses treatment in another Member State, although retrospective applications may also be considered.

12.3 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 prior authorisation. We will advise patients in guidance to have a conversation with their local NHS health professionals before travelling for treatment.

12.4 This process of authorisation enables the patient to confirm that they are entitled to the treatment they want to receive in another part of the EEA, as well as the level of reimbursement they can expect. It also gives NHS healthcare providers the opportunity to ensure that patients are aware of all of the possible treatment options within the NHS, which may 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 rights to seek treatment in the EEA are entitled to do so and to apply for reimbursement, subject to the conditions and limits set out in legislation.

12.5 Under existing legislation, reimbursement for certain types of specialised or cost intensive treatment or services is subject to the patient obtaining prior authorisation. And authorisation must be granted where the NHS cannot provide the treatment without undue delay.

12.6 Therefore, to ensure that the Directive provides a sustainable framework for cross-border healthcare and that Member States can manage their healthcare systems effectively and appropriately, the Scottish Government believes that prior authorisation systems are a sensible and necessary measure.

12.7 The Directive permits Member States to adopt a system of prior authorisation, which meet the conditions set out in Article 8(2), where:

- (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. general 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 outcomes in a particular procedure*)

12.8 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 that demonstrates the categories of healthcare satisfy the criteria. Under current domestic legislation, in sections 75B, 75C and 75D of the NHS (Scotland) Act 1978 the right to reimbursement of the cost of some healthcare, defined as “*specified services*” 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 is set out below.

Discretion to refuse prior authorisation in certain cases

12.9 Article 8(6) sets the criteria for refusal of prior authorisation for treatment requested under the terms of the Directive. Refusal of prior authorisation is only permitted in only 4 circumstances:

(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.

12.10 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 could be applied as 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.

12.11 Criterion (d) above can be summed up as “where there is no undue delay” and presents difficult issues that need to be considered carefully.

12.12 It essentially means that 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-scale based on a clinical assessment of the individual patient’s condition and not merely by reference to a general waiting time.

12.13 The European Court of Justice, in previous cases (notably in *Watts - v - the UK*) has said that refusal of prior authorisation is permitted where treatment can be provided within the home system in these circumstances. Some parts of the NHS could find it helpful to use this provision 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 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.

12.14 Essentially, the Directive starts from the premise that the use of systems of prior authorisation should 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:

- to identify those categories of healthcare that we can demonstrate satisfy the criteria in Article 8(2) - i.e. subject to prior authorisation; and
- to ensure that if we adopt the discretion to refuse authorisation, where the NHS can provide 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.

12.15 Research commissioned by the Department of Health and conducted over 2009/10 (by the Health Economics Consortium at the University of York) concluded that many NHS healthcare providers lacked understanding and clarity about patients’ rights under EU law and their entitlement to reimbursement. While knowledge in this regard has increased in recent years, following the publication of the draft Directive and its subsequent adoption, there is still a need to educate both the Service and the public. We need to provide clarity to NHS Boards around the limits of the powers to refuse prior authorisation and what they must do when a decision to refuse is made.

12.16 The process of applying prior authorisation in individual cases would be handled by territorial NHS Boards in Scotland. When the criterion of “where there is no undue delay” was to be used to justify refusal of authorisation, it would be necessary for the decision letter to set out the reasons in full, explaining why the decision maker had concluded that the NHS could provide the treatment within a medically justified period of time. We anticipate that in using this criterion, the NHS would be expected, in each individual case, to specify in writing the medically justified period of time during which treatment must be provided based on 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 guarantees, whether national or local.

Options

12.17 This is a complex measure and we recognise that there will be legitimate interests within the NHS and beyond on how (or whether) Article 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

12.18 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 some 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.

12.19 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.

12.20 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 Article 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.

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

12.21 This option would limit application 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 would demonstrate that in adopting this system a balanced and proportionate approach was being taken. This option would limit any 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.

12.22 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.

12.23 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 should not be confused with waiting time guarantees or averages within the home 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)

12.24 This preserves the central ethos of freedom of movement of EU citizens, which underpins this Directive and would ensure that there was limited administrative risk of the NHS imposing unreasonable restrictions, which would constitute obstacles to the freedom of movement of patients. However, by not adopting Article 8(6)(d) we would have less control on specialist and sometimes expensive services.

12.25 The Scottish Government’s current thinking is that we either adopt:

Option (i) - this would require careful management, perhaps with decisions taken centrally, if it were to 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; or

Option (ii) - with a limited list of services for prior authorisation and clear evidence to patients’ as to why they might be refused authorisation.

However, we would welcome your views on the three options.

Consultation questions

- **Do you have a view on whether or how the Scottish Government should adopt the Article 8(6)(d) derogation?**
- **Should the derogation (if taken) be limited to the list of services?**
- **Do you believe this Article can be made to work in practice?**

Categories of treatments subject to prior authorisation

12.26 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.

12.27 For the categories of "treatments subject to prior authorisation", Member States 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.

12.28 We take the view that prior authorisation will not be applicable generally to services such as primary care, dentistry and optometry. 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 set out in Options (i) and (ii) above.

Specialised & High Cost Services

12.29 Although the majority of NHS services in Scotland are commissioned by NHS Boards there are different arrangements for commissioning what are called "specialised services". National Services Division (NSD) is a division within NHS National Services Scotland. Each year, NSD receives ring-fenced funding from the Scottish Government to commission and performance manage nationally designated specialist services and screening programmes.

12.30 National commissioning is reserved for those specialist services where local or even regional commissioning is not appropriate. The services are generally concerned with the diagnosis and / or treatment of rare conditions.

12.31 NSD also funds services provided in England through two distinct funding streams:

a contribution to the National Specialised Commissioning Team (NSCT) for Scottish access to designated highly specialist services which are provided on a UK basis; and

by managing a pool of funds (risk share scheme) on behalf of NHS Boards for specialised services in England which are not nationally designated.

12.32 A full list of nationally funded services is available at:

<http://www.nsd.scot.nhs.uk/services/specialised/index.html>.

There would seem to be some symmetry in aligning this list of specialised services with the categories for prior authorisation. However, there will 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 (PET-CT, 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 Scotland should continue to operate a system of prior authorisation for patients requiring certain types of medical treatment or services**
- **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?**

Interaction with Directive 883/2004

12.33 Significantly, Article 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 (the S2 route). 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.

12.34 NHS Boards will need to consider the relevant aspects of both the Regulation and Directive routes. The language at Article 8(3) may need to be simplified or clarified, but this clause will need to be reflected in the implementing regulations (and underpinned by guidance).

Rare Diseases

12.35 Article 8(4) then 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 in the rare disease in question, or the expert's opinion is inconclusive, the home state **may** seek scientific advice of experts in another State. This clause reflects the European 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 5:10,000). However, this is discretionary and is not a binding obligation. Therefore it will not form part of the implementing legislation.

Article 9 - Administrative procedures regarding cross-border healthcare

13.1 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 to set out a decision making period of 21 days in the guidance that will underpin the domestic implementation regulations (unless further information is required). As with the current arrangements, decisions on requests must be challengeable, both by administrative review and judicial proceedings.

13.2 In the guidance we will also capture the way in which NHS Boards 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.

13.3 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 whether or not the existing mechanisms under Regulation 883/2004 are more appropriate to the patient's particular circumstances.

13.4 We believe there is a benefit for patients to have a dialogue with their local NHS Board about entitlement and reimbursement levels (and we would encourage them to do so), but we are aware that any mandatory requirement to do so is likely to be disproportionate. However, there may be some merit in a voluntary system, operated by NHS Boards which encourages the correct dialogue to take place between patient and the NHS Board in advance of treatment not subject to mandatory prior authorisation and we welcome views on this proposal

Consultation question

- **Is the proposal for a decision making period of 21 days reasonable? If not, what would be a reasonable timescale?**
- **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 co-operation

14.1 This Article needs to be read (and transposed) in conjunction with Articles 4 & 6.

It requires Member States to co-operate 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.

14.2 The Member State of treatment must, on request from other 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 existing Commission Internal Market Information (IMI) system. This is now obligatory for this Directive and all component authorities that would be exchanging such information should be using the IMI system.

14.3 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 at the time has not been charged or is not the subject disciplinary / court action etc. We welcome the views of respondents on this issue.

Consultation questions

- **What information should be shared between competent authorities, and in what circumstances?**

Article 11 - Recognition of prescriptions issued in another Member State

15.1 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 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.

15.2 Article 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;

15.3 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. Article 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.

15.4 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 Article 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.

15.5 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.

15.6 The new non-exhaustive list 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.

15.7 The UK Government intend to amend UK-wide medicines legislation to adopt the non-exhaustive list for both incoming and outgoing cross-border prescriptions. 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

15.8 During negotiations on the this 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 Article 11(6).

15.9 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 - prescription only medicines (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 UK Government's and Scottish Government's opinion, no compelling need to make such a designation was identified.

15.10 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 SMP - and therefore remain excluded from EEA prescriptions.

15.11 The changes will be implemented by way of an amending UK-wide 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.

15.12 Provisions are in place in domestic legislation that provide much of what Article 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

16.1 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 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 expertise.

16.2 Participation is voluntary, albeit expected and encouraged and as with Article 8(4), the Commission's key focus of attention is advancing the agenda on rare disease. Article 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.

16.3 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.

16.4 In terms of Directive implementation, no implementing legislation is required in this area. Whatever results from this work 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

17.1 Article 13 was a late addition to the Directive to strengthen the message on pan-European co-operation 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 - e-Health

18.1 Article 14 is intended to support and facilitate co-operation and the exchange of information among Member States working within a voluntary network on the e-Health agenda, on 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;
- draw up guidelines on, a non exhaustive list of data to be included in patient summary records which can be shared across borders;
- identify effective methods for enabling the use of this information for public health and research; and
- develop common identification and authentication measures to facilitate cross-border healthcare.

18.2 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 8 May 2012 in Copenhagen. However, measures adopted will not interfere with Member States' competence in implementing e-Health systems or harmonising national laws and are not mandatory.

18.3 In terms of Directive implementation, no implementing legislation is required in this area. Whatever results from this work 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 - Co-operation on health technology assessment

19.1 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' co-operation in HTA at EU level through a series of EU-funded projects, and most recently, the Joint Action on Health Technology Assessment 'EUnetHT' (more information about EUnetHT can be accessed through the website: 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). The Scottish Medicines Consortium also has a watching brief.

19.2 Scotland supports international collaboration in HTA and welcomes the Commission's support for on-going 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 for the organisation, funding 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.

19.3 Sharing of information and methods, and stream-lining of information requirements are likely to be the most valuable and productive areas for continuing cooperation in HTA at EU level. The Scottish Government 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.

19.4 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

Consultation questions

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

Articles 16-19 - Committee & delegated acts

20.1 Much of the detail in these articles is about Commission procedures. They deal with the powers of the Commission (Article 17) and objections to the powers proposed (Article 18). Nothing in articles 16-19 requires implementation into UK law.

Article 20 - Reports

21.1 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.

21.2 There are specific requirements for the Commission to report on how the use of the provisions on limiting the application on rules on reimbursement for reasons of general interest (Article. 7(9)), prior authorisation (Article 8) and on the functioning of National Contact Points and European Reference

Networks (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.

21.3 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) (Article 6) and national authorities. We understand that the Commission intends specifying a range of data and information about the uptake and use of the Directive, which Member States will be asked to collect.

Article 21 - Transposition

22.1 This requires Member States to transpose the Directive into their national law 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 25 October 2013.

Part 2

Respondent Information Form and consultation questions

CONSULTATION ON SCOTLAND'S TRANSPOSITION AND IMPLEMENTATION OF DIRECTIVE 2011/24 EU ON THE APPLICATION OF PATIENTS' RIGHTS IN CROSS-BORDER HEALTHCARE



RESPONDENT INFORMATION FORM

Please Note this form **must** be returned with your response to ensure that we handle your response appropriately

1. Name/Organisation

Organisation Name

Title Mr Ms Mrs Miss Dr *Please tick as appropriate*

Surname

Forename

2. Postal Address

<input type="text"/>		
Postcode	Phone	Email

3. Permissions - I am responding as...

Individual / Group/Organisation

Please tick as appropriate

(a) Do you agree to your response being made available to the public (in Scottish Government library and/or on the Scottish Government web site)?

Please tick as appropriate Yes No

(b) Where confidentiality is not requested, we will make your responses available to the public on the following basis

Please tick ONE of the following boxes

Yes, make my response, name and address all available

or

Yes, make my response available, but not my name and address

or

Yes, make my response and name available, but not my address

(c) The name and address of your organisation **will be** made available to the public (in the Scottish Government library and/or on the Scottish Government web site).

Are you content for your **response** to be made available?

Please tick as appropriate Yes No

(d) We will share your response internally with other Scottish Government policy teams who may be addressing the issues you discuss. They may wish to contact you again in the future, but we require your permission to do so. Are you content for Scottish Government to contact you again in relation to this consultation exercise?

Please tick as appropriate

 Yes

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 (page 9)

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

Responsibilities of Member State of affiliation (page 15)

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 (page 18)

6. 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?
7. What will be the impact of providing clear and transparent information on the volume of patients who may wish to access cross-border healthcare? Please provide evidence where possible.

General principles for reimbursement of costs (page 20)

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

Healthcare that may be subject to prior authorisation (page 23)

11. Do you agree that the UK should continue to operate a system of prior authorisation for patients requiring certain types of treatment?
12. 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?
13. What is the evidence to support this inclusion?
14. Do you have a view on whether or how the Scottish Government should adopt the Article 8(6) (d) derogation?
15. Should the derogation (if taken) be limited to the list of highly specialised services only?
16. Do you believe this Article can be made to work in practice?

Administrative procedures (page 30)

17. Is the proposal for a decision making period of 21 days reasonable? If not, what would be a reasonable timescale?
18. 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?
19. What would such a system look like and how could it work in practice?

Mutual assistance and co-operation (page 31)

20. What information should be shared between competent authorities on treating practitioners, and in what circumstances?
21. How do you think the European reference networks and proposed e-health and health technology assessment networks might best add value to Scotland?
22. What impact might these have on current Scottish systems?



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ISBN: 978-1-78256-486-7 (web only)

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Produced for the Scottish Government by APS Group Scotland
DPPAS14108 (03/13)

Published by the Scottish Government, March 2013

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