Department of
Health, Social Services and Public Safety
www.dhsspsni.gov.uk

Cross Border Healthcare & Patient Mobility

Consultation on the Implementation of Directive 2011/24 EU

(on the application of patients' rights in cross-border healthcare)

Responses are invited by 13 September 2013

July 2013

Content **Page No**

Annexes **Page No**

Executive Summary

Directive 2011/24 EU clarifies citizens' rights to access healthcare in another Member State of the European Economic Area (EEA) and 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.

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.

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 Department's overall approach to implementation, as well as how it proposes to meet the individual obligations contained in the Directive.

1. Purpose of Consultation

1.1 This consultation document sets out the Department of Health, Social Services and Public Safety's (the Department) 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 the accompanying equality screening and regulatory impact assessment considering the particular effects the proposed approach may have on Northern Ireland's health system. Overall implementation of the Directive is being led by the Department of Health in England as the central Whitehall department which negotiated the Directive. Our Department has been closely involved with the Directive from its beginning and throughout the negotiation process. This consultation aims to take account of the overall UK position on the Directive but also includes some specific implementation approaches that are more appropriate for Northern Ireland in the context of the fact that a land-border exists with another EU member state, namely the Republic of Ireland, which does not have a similar style of health service provision.

1.2 The Directive clarifies citizens' rights to access healthcare in another Member State of the European Economic Area (EEA) (the Member States of the European Union plus Iceland, Liechtenstein and Norway), sets out the grounds on which they can claim reimbursement of the eligible costs of treatment from their home health system and is clear about the limits and conditions on reimbursement that Member States may place on patients who wish to access healthcare in another EEA State. The Directive also sets out a number of areas for EU-wide cooperation in healthcare.

1.3 The purpose of the Directive is not to foster or promote cross-border healthcare but to facilitate the exercise of patient choice to access healthcare services in another Member State and to ensure that they are safe and of high quality when citizens decide to use the Directive's provisions to access necessary healthcare. The Directive also aims to help patients benefit from improved information and better clarity on the rules that apply.

1.4 Although there is a final adopted text for the Directive, it is for each Member State to decide how it is implemented at national level. There is considerable scope to decide how best to implement the Directive's requirements into the domestic system and for each UK country to implement the Directive's obligations in a suitable way for their own local health system. From the outset, while the Department has tried to maintain parity with the adoption of much of the Directive across the other three UK countries, it has been necessary in some instances to nuance implementation of the Directive to take account of the proximity of Northern Ireland to another EU member state, namely the Republic of Ireland which does not have an entirely analogous healthcare system free at the point of delivery. This consultation document sets out the Department's overall approach to implementation, as well as how it proposes to meet the individual obligations contained within the Directive.

2. Introduction

2.1 The majority of EU citizens receive healthcare in the Member State where they live, via the health system through which they are covered or insured. However, in some instances, it may benefit the patient to obtain healthcare in another European country, where there may be better expertise available, lower costs, better availability of certain highly specialised treatments or where waiting times are shorter.

2.2 EU regulations on the 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 in another country.

2.4 Over the last fifteen years, there have been more than a dozen high profile legal cases in which Member States' interpretation of the rules in respect of obtaining

healthcare across borders has been questioned and on which the European Court of Justice (ECJ) has been asked to make a determination. The development of this case law based on individual cases (including one in 2006 against the UK in the case of Yvonne Watts vs. Bedford PCT, which the UK lost - *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"*), 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 the ECJ case law and applies best practice in providing access to these rights. The Council of Ministers and the European Parliament adopted the Directive on 9 March 2011. Its main objectives are to:

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

2.6 The Directive sets out the information Member States must provide for patients from other states considering coming to the country to purchase health care. It also sets out the arrangements that a Member State must provide to allow its own citizens to access their rights to reimbursement of the costs of cross-border healthcare where they choose to seek health care in another Member State. It also provides clarity on the information a Member State is required to provide to citizens of other states considering coming to their country. Crucially, the 'home' state retains responsibility for deciding what healthcare it will fund, so the Directive is not a way for citizens to

gain entitlement to treatments that would not normally be available under their home health service. In addition, Member States are required to be clear and transparent in home legislation or administrative process as to what entitlements to healthcare home patients have within their own health system.

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

3. Previous consultations & reference material

The European Commission's original proposal for a Directive

3.1 The Department of Health in England consulted on the first draft of the Directive when it was published in 2008. That consultation set out the rationale for the Commission's intervention in this area, the measures being proposed to make cross-border healthcare a success for European citizens and respondents were requested to contribute views to inform negotiations on the Directive.

3.2 The consultation documentation (including a partial impact assessment) and the UK Government's response to it are available to download from the Department of Health website at the following links:

http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Consultations/Closedconsultations/DH_089029

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_089032.pdf

House of Lords European Committee

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

http://www.official-documents.gov.uk/document/cm75/7580/7580.pdf

The Health Care (Reimbursement of the Cost of EEA Services etc.) Regulations (Northern Ireland) 2012

3.4 In 2012, the Department ran a limited consultation with the health service on the scope and application of a set of draft regulations and accompanying directions [and guidance] to implement the judgment of the European Court of Justice in Case C-372/04 - the Queen on the application of Yvonne Watts v Bedford Primary Care Trust and the Secretary of State for Health.

3.5 This limited consultation requested views from within the health service 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 renumbered Article 56) of the Treaty. Following consideration of the consultation responses, the Regulations were made, accompanied by directions and guidance. These came into operation in May 2012. The consultation documentation is available to download from the Departmental website at the following link:

http://www.dhsspsni.gov.uk/showconsultations?txtid=53895

4. Devolved Policy and Reserved Policy

4.1 While the Secretary of State for Health in England retains overall competency to legislate for the Devolved Administrations on EU matters (reserved under the Devolution agreements), the Secretary of State's powers to legislate and direct on behalf of the Devolved Administrations in connection with health matters are limited. Given the Directive's focus on healthcare, the Department will be introducing all the necessary domestic legislation to bring into effect the requirements of the Directive for Northern Ireland.

4.2 However, for some elements of the Directive's implementation, for example provisions relating to professional indemnity and the recognition of prescriptions, it is more appropriate that these are carried forward by the Department of Health in England on behalf of all four countries given the UK wide nature of the legislation. These issues will be discussed further within this consultation document.

5. Implementing Directive 2011/24 EU Summary

5.1 The Directive seeks to clarify the numerous case law precedents that have been established over a number of years by the European Court of Justice (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.

5.2 Member States are responsible for ensuring that their national legislation is consistent with European law. Where it is not, they must amend existing provisions and introduce new law where necessary. Where EU legislation has not been effectively implemented, Member States may risk legal action and corresponding financial penalties (known as "infraction" proceedings).

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

5.4 The basic structures put in place by the 2012 interim EEA Regulations in terms of the Board providing the function of prior-authorisation and reimbursement will not be altered by implementation of the Directive.

5.5 A further set of regulations is required to implement the main provisions of Directive 2011/24/EU (the subject of this consultation). Following consideration of responses to this consultation, the intention is that the regulations would come into operation by 25 October 2013 (the transposition deadline).

5.6 These implementing regulations will not deal with the requirement for indemnity insurance or similar such arrangements in Article 4 of the Directive, or the Article 11 requirements on 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 in England on a UK-wide basis.

6. Article by Article discussion

6.1 The following paragraphs look at each of the relevant Articles within the Directive providing an explanation of each Article, alongside some commentary on the Department's perspective. Where relevant we have highlighted specific questions we are seeking feedback on in relation to the consultation, however, these are not exclusive and we would welcome and consider comments on any aspect of the Directive as laid out in this consultation document.

Consultation question

1. What proportionate measures can the Department 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 Northern Ireland patients as well as the impacts this has on the health service (budget, administrative costs, commissioning etc).

7. Article 1 – Subject matter and scope

7.1 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).

7.2 The Directive covers treatment for long-term medical conditions (e.g. for dialysis, diabetes, epilepsy etc), which are within the scope, but not services which are described in Northern Ireland domestic arrangements as "social care" provision (e.g. personal care). 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.

8. Article 2 – Relationship with other European Union provisions

8.1 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.

9. Article 3 – Definitions

9.1 Article 3 defines the terms used in the Directive. In preparing the draft Regulations to implement the Directive, these definitions will be used where appropriate. However, where there are existing domestic legislative definitions these will be used instead.

9.2 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”). The aim will be to make the domestic provisions as clear as possible for use within the health service and by patients who are considering using these rights.

10. Article 4 – Responsibilities of the Member State of treatment

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

- provide patients with relevant information on treatment options and quality and safety;
- provide clear invoices and price information;
- apply fees in non-discriminatory manner;
- ensure transparent complaints procedures, and procedures to obtain redress;
- apply adequate systems of professional liability insurance or similar;
- respect privacy in the processing of personal information;
- supply patients with a copy of the record of their medical treatment.

10.2 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

10.3 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.

10.4 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.

10.5 The definition of “healthcare professional” in the Directive is “a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Directive 2005/36/EC or a person considered to be a health professional, according to the legislation of the Member State of Treatment.

10.6 Therefore, in accordance with UK wide legislation regulating health professionals, the requirements on "healthcare providers" will apply to "healthcare" provided in the UK by any registrant of the following statutory healthcare regulators, whether as an individual or as an employee of a legal entity:

- General Chiropractic Council
- General Dental Council
- General Medical Council
- General Optical Council
- General Osteopathic Council
- Health and Care Professions Council
- Nursing and Midwifery Council

- Pharmaceutical Society of Northern Ireland
- General Pharmaceutical Council

10.7 A full list of the professions regulated by domestic legislation may be found at Annex A of this document.

Consultation question

1. Are there any other "health professions" operating in Northern Ireland to which the provisions of the Directive will apply when treatment is supplied here?

Obligations on providers

Professional regulation

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

RQIA Registration

10.9 In Northern Ireland, providers are currently registered with RQIA where they are providing a particular type of establishment or agency. This means that if a provider - whether public or independent/private falls within the establishments and agencies laid down in The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, then they are required to register with and be regulated by the RQIA. Some providers covered by RQIA registration will not be relevant for the purposes of the Directive given that they do not provide services

which fall within the definition of healthcare laid down in the Directive. As such for the purposes of the Directive the RQIA Regulated establishments are;

- a day care setting;
- a nursing home;
- an independent clinic; or
- an independent hospital.

Regulated agencies are;

- a domiciliary care agency;
- an independent medical agency; or
- a nursing agency.

The Department believes that most, if not all, incoming cross-border patients wishing to use health services or private facilities in Northern Ireland, apart from hospitals or health service clinics, will come within services provided by the above regulated establishments and agencies.

10.10 Therefore all likely healthcare providers, except health service hospitals or clinics - whether public, independent or private - engaging in/providing any service described above, are required to register with RQIA and be bound by the relevant standards. In this, all of the Article 4 obligations map directly to RQIA registration requirements, with the exception of professional indemnity insurance (however, see the discussion below on how the particular requirements of Art.4(2)(d) will be delivered).

10.11 Therefore, for all providers that are required to register with RQIA, there is a mechanism in place to enforce these parts of the Directive - and this applies equally to providers regardless of whether they are state or private sector providers.

Health professional regulation

10.12 While RQIA registration provides a high level of assurance, RQIA coverage will only apply to those providers that require RQIA registration - not health service hospital or clinics. It is envisaged that those establishments and agencies governed by RQIA registration are likely to provide services which will form the principal area of activity,

outside of health service hospitals and health service clinics, in relation to cross-border healthcare and is defined with reference to the following healthcare professionals:

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

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

- Establishing standards of competence, ethics and conduct;
- Establishing standards for training;
- Keeping a register of those who meet the standards;
- Dealing with registrants who fall short of the standards required through fitness to practice action: e.g. by placing conditions on their registration or removing them from the register.

10.14 The health regulators produce a variety of standards, guidance, codes of practice and codes of conduct that govern the way in which their registrants are required to act as a regulated professional. As such, health professionals are under a duty to abide by the terms and provisions of these documents. If they do not, and should a complaint be received about their conduct or performance, then the regulatory bodies can take account of whether the standards have been met when they decide whether it would be appropriate to take fitness to practice action to protect the public.

10.15 Thus, the Department believes that a very high level of regulatory coverage is ensured for cross-border patients seeking certain healthcare services in Northern Ireland. (RQIA registration is relevant only for Northern Ireland, different systems of regulation exist in England, Scotland and Wales).

Delivering the Article 4 obligations

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

10.16 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.

10.17 What is "relevant information" is not specified, in either Article 4 or elsewhere in the Directive. The idea behind NCPs is to establish a network of such bodies across the Community to facilitate patient access to information and services. To a large

extent, this is an area where Member States will need to co-ordinate their approach, since a degree of uniformity of provision and practice across the Community will be required. The Department continues to have these discussions with the other UK health departments as well as the EU Commission.

10.18 Therefore, the proposed approach is to implement Art.4(2)(a) into domestic legislation almost as it stands, as a package of legislative measures aimed at setting the role and functions of the NCP (but see also discussion around Article 6 further on in this document). With a view to providing detailed guidance on "how" the NCP will go about its business.

10.19 The Department's 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 all these provisions on the role and functions of the NCP together in the Regulations (see also discussion around Article 6 further on in this document). Detailed guidance would then be provided on "how" the NCP would go about its business.

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

10.20 The Directive requires healthcare providers to provide patients with clear information on prices and clear invoices. Providers cannot make up a price or seek to charge more simply because the person is an EEA patient seeking treatment under the Directive.

10.21 In terms of how these requirements are met, for secondary care provided by the health service, relevant health service bodies should recover the full cost of the treatment given to an EEA patient under the Directive, and this may include an element to cover reasonable costs of administration. Member States must have a transparent mechanism for the calculation of costs for cross-border healthcare which must be based on objective, non-discriminatory criteria known in advance. The Department will produce a schedule of costs, based on Human Resource Group

(HRG) unit costs, where available, or the appropriate unit cost for out-patient or community treatment. Where no HRG or other unit cost exists, a cost will need to be worked out and average costs which can be shown to have been objectively calculated in a transparent way may be used.

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

General Medical Services

10.23 Generally, in GP and GP out of hours services, if an EEA national is treated as a health service patient (as they will be if requiring immediate treatment on a visit, or exercising a treaty right here, apart from when they specifically request to be treated on a private basis), then that treatment/consultation is free of charge. Under Article 4,2 of the Directive it is clear that patients do not have to be accepted for treatment in primary or secondary care where there is no capacity to treat them but that where capacity exists patients may be treated and charged for the service. Essentially, the Directive requires the treating Member State to ensure that patients from other Member States are charged the same price that usually applies to a domestic patient in a comparable situation. Therefore, providers including primary care providers must apply the same scale of fees for healthcare to EEA patients as for domestic patients. If there is no comparable price for domestic patients, a price may be created so long as it is based on objective, non-discriminatory criteria (Art.4(4)) – as no charge is presently levied for GP treatment a charge would need to be constructed.

10.24 As a result of the Directive, some amendments to the current GMS Contract Regulations will be necessary so as to allow patients to obtain treatment with a GP in Northern Ireland (where capacity exists to see that patient) while also setting down

a fee representative of health service costs to the system for that care. The Department is working with the Board to identify the necessary operational processes and charging arrangements that must be put in place within primary care to satisfy this requirement of the Directive. Furthermore, arrangements will also need to be put in place by the Board to facilitate patients coming to Northern Ireland under the Directive in terms of access to out-of-hours GP services and levying suitable charges for care. In this respect, the Department can look to the learning and experience gained from the out-of-hour project set up under the North South Ministerial Council (NSMC) arrangements which allows patients from the Republic of Ireland and Northern Ireland to access an out-of-hour GP centre in a locality closer to them on the opposite side of the border to which they live. It will not be practicable or possible for all services to be offered to Directive patients in respect of primary care for example, home visits to patients by GP practices. However, where reasonably practicable, practices should offer Directive patients treatment which is clinically appropriate for them on an adhoc basis - Directive patients will not be entitled to register as health service patients.

General Dental Services

10.25 In respect of health service dentistry similar amendments will be required to the General Dental Services Regulations which will allow patients coming to Northern Ireland under the Directive to receive health service dental treatment but also to have a suitable charge specified that must be charged to Directive patients. Again, Directive patients will be able to obtain adhoc dental care but will not be fully registered health service patients. Presently charges levied to Northern Ireland patients are set out in the Statement of Dental Remuneration (SDR) available at:

http://www.dhsspsni.gov.uk/statement_of_dental_remuneration__2012_-_2013.pdf

However, the SDR charges do not reflect the full health service cost of providing dental services on the system as additional costs are also covered by the Board. As far as Directive patients are concerned, the charge raised will be inclusive of the normal patient charge along with additional charges which factor in the contribution

normally made by the Board to the dental practice. The Department is of the view that the specific exemptions from charge for dental services will not be applied to patients seeking health service dentistry in Northern Ireland under the Directive.

General Ophthalmic Services

10.26 In relation to optical treatment, the majority of Northern Ireland patients have to pay for eye sight tests and high street optical services, apart from some groups of patients who are entitled to free sight tests and optical vouchers to help with the cost of glasses or contact lenses. Similarly, certain groups of patients who are on low incomes or in receipt of certain benefits have entitlement to free dental services. The general rules are set out at NI Direct: http://www.nidirect.gov.uk/help-with-health-costs

10.27 The Department proposes that the exemptions from charge which apply to these specific categories of patient would not be applied to patients seeking primary care services in Northern Ireland under the Directive. The detail of how the principle of charging and charge collection in primary care services will work for Directive patients will be set out in the accompanying guidance with the implementing legislation for the Directive. In terms of pharmaceutical care in Northern Ireland all those entitled to health services and resident in Northern Ireland can presently avail of free prescriptions. As noted already the health service does not have to offer free treatment to patients travelling here and exercising their Directive rights but rather an objective charge may be levied that represents the cost of providing a particular drug to a Directive patient.

10.28 Pharmacists in Northern Ireland already recognize prescriptions issued in other EU countries under the current EU rules that allow pharmacists to recognize prescriptions from elsewhere and these are dispensed on a private basis. It is the Department's proposals that any patient who receives primary care under the Directive in Northern Ireland for example, attending a GP practice and requiring a

prescription would also have this dispensed privately. This is not withstanding the Department's intention to examine and review the usage levels of primary care services including prescriptions by Directive patients with a view to charging prescriptions' at a health service rate at some point in the future. The Department is working with the Board to establish the feasibility of introducing health service chargeable prescriptions for Directive patients taking account of the current timeframes and whether a system could operate within HSC.

Private/independent providers

10.29 An EEA patient seeking treatment in the UK may also wish to access services in the independent sector, which is not governed by the same charging principles as the HSC. Nevertheless, the Directive obligations on clear pricing apply equally to health care provided to a visiting patient by either the public or private sector. Where a Member State already provides for patients resident in the State with relevant information on these matters, the Directive does not oblige a Member State to provide more extensive information to visiting patients.

10.30 The Department considers that the obligation on clear information on prices and invoices can be satisfied by consumer protection legislation, in particular, the Consumer Protection from Unfair Trading Regulations 2008. These set out the rules that apply to consumer protection and the responsibilities on businesses to trade fairly. The Regulations implement the Unfair Commercial Practices Directive (2005/29/EC) in the UK and set a general duty not to trade unfairly, as well as ensuring that traders act honestly and fairly towards their customers and apply primarily to business to consumer practices. If a trader misleads or otherwise acts unfairly towards consumers, then the trader is likely to be in breach of the Regulations and may face action by enforcement authorities (in the UK, the Office of Fair Trading). Both civil and criminal enforcement is possible under the Regulations.

Non-discrimination

10.31 Article 4 requires non-discrimination with regard to nationality; in particular, Art.4 (4) requires the treating Member State to ensure that patients from other Member States are charged the same prices that apply to a domestic patient in a comparable situation. Healthcare providers must therefore apply the same scale of fees for healthcare to EEA patients as for domestic patients. If there is no comparable price for domestic patients, the price must be based on objective, non-discriminatory criteria (Art.4 (4)).

10.32 This also means that independent providers who deliver health services would only be able to charge the same price as that for domestic health service patients, should an EEA patient seek treatment as if they were a health service patient. They will only be able to charge the patient as a private user if the patient has specifically asked to be treated privately. Providers cannot refuse to treat an EEA patient on the grounds of nationality but may do so where the delivery of such treatment would cause significant detriment to home patients waiting for similar treatment, or where there is insufficient capacity to treat additional non-Northern Ireland patients (Art.4(3).

10.33 The Race Relations (Northern Ireland) Order 1997 prohibits direct or indirect discrimination in the provision of services (whether for payment or not) on grounds of race. Article 5,1 of the Order defines racial grounds to include colour, race, nationality or ethnic or national origins.

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

10.34 For HSC bodies, there is a central HSC Complaints Procedure, information on which is available through the NI Direct website:

http://www.nidirect.gov.uk/index/do-it-online/health-and-well-being-online/make-a-complaint-against-the-health-service.htm

10.35 Complaints about individual health professionals can also be made to the appropriate regulatory body.

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

10.36 4(2)(d) sets out requirements about systems of professional liability insurance (or similar such arrangement). This means that any health provider or individual health professional, not already covered by vicarious arrangements, must have an appropriate level of indemnity cover and make this known to the incoming patient. This is a policy area that has already been evolving separately in the UK centrally following the 2010 "independent review of the requirement to have insurance or indemnity as a condition of registration as a healthcare professional". The Department along with the other UK health Departments 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, in the main this work is UK-wide in scope. However, Northern Ireland will be making its own arrangements for the professional indemnity coverage for pharmacists registered with the Pharmaceutical Society of Northern Ireland given the different way in which pharmacists are regulated in Northern Ireland. This issue will be consulted on and legislated on separately by the Department but will be correlated to ensure that the necessary measures are in line with the overall transposition date of 25 October 2013.

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

10.37 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 including, providing a copy of the record of treatment for the

cross-border patient to take away (back to their own Member State for follow up with their own clinicians).

10.38 The Data Protection Act 1998 (as amended) provides safeguards on the protection of personal information and the right for a patient to request a copy of their health records. The right can also be exercised by an authorised representative on the individual's behalf. This legislation is UK-wide in scope. Data Protection legislation defines a health record as a record consisting of information about the physical or mental health or condition of an identifiable individual made by, or on behalf of, a health professional in connection with the care of that individual.

10.39 A health record can be recorded in computerised or manual form or in a mixture of both. It may include such things as, hand-written clinical notes, letters to and from other health professionals, laboratory reports, radiographs and other imaging records e.g. X-rays and not just X-ray reports, printouts from monitoring equipment, photographs, videos and tape-recordings of telephone conversations. Data Protection legislation is not confined to health records held for 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.connectingforhealth.nhs.uk/systemsandservices/infogov/links/gpelec2011.pdf

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_112916

Other general principles

10.40 Article 4 confirms that the Member State of treatment is not required to provide treatment to anyone where this would undermine significantly the treatment of home patients. Art.4(3) also confirms that, where justified by overriding reasons of general interest (such as planning requirements or the wish to control costs), the Member

State of treatment may adopt measures controlling access to treatment where this is necessary and proportionate. This could not be an arbitrary decision and would need to be supported by clear evidence on the effects of cross-border healthcare on the home system.

10.41 Member States may also provide information in other EU languages if they choose to do so. The Department proposes to cover all of these points in guidance.

10.42 Taken together, it is the Department's view that the comprehensive basket of provisions set out above meet fully the Directive's obligations on the responsibilities of the Member State of treatment.

11. Article 5 – Responsibilities of the Member State of affiliation

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

11.2 It is critical here to remember that the Directive is about the rights of patients in exercising personal choice to go to another EEA country to access healthcare and seek reimbursement of those costs where the treatment in question would have been made available to the patient in Northern Ireland on the health service here. Importantly, it is not about the health service formally commissioning healthcare for patients in other EEA Member States. Separate rules exist to regulate this, for example, when the Board decide to approve individual funding requests for patients

to go outside Northern Ireland for treatment given their particular clinical condition. In choosing to access healthcare in another Member State, the home patient is effectively stepping outside of the health service system and using their rights under EU law to seek healthcare elsewhere. At this point, the patient is taking individual responsibility for ensuring that the service they obtain is appropriate and safe within the laws of the country of treatment (not under UK legislation). The Board under this legislation, will not be commissioning services from providers abroad and will not be liable for the outcome of the treatment provided.

11.3 The implementing regulations will need to impose the duties set out in Art.5 on relevant health service bodies, such as the Board.

Publicising information on rights

11.4 In terms of making information on rights and entitlements publicly available, the Department needs to consider what the most appropriate communication channels are for Northern Ireland residents. Currently, both NI Direct and the Departmental website are central to how the Department puts messages out to the general population. At the moment, some limited information is provided to the public on the current options for treatment in the EU at:

http://www.dhsspsni.gov.uk/advice-for-patients

11.5 The information on this web site will be revised to take account of the implementation of the Directive and to give greater emphasis on individual rights and the processes in place. Given its pivotal role in terms of cross border healthcare it will also be necessary for the Board to publish information on the procedures and processes to be followed on its website.

11.6 The Department will also work in conjunction with the Health and Social Care Trusts and primary care providers, to ensure that all parts of the health system respond effectively and appropriately to patient requests.

Information on establishing entitlement(s)

11.7 Limited information exists presently as regards patient entitlement to services within Northern Ireland. The Department has created interim regulations which recognise the rights that patients have to go elsewhere in the EEA for healthcare and information has been made available to patients to explain this right via the Departmental website.

11.8 However, the Directive is clear that patients need to have a much clearer idea of their entitlement to services before they travel abroad for care and the Department recognises the need to move towards a much more transparent entitlement framework.

Issues

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

11.10 The Directive does not allow health service patients to go anywhere within Europe and get any treatment (or drug) they may desire and then seek reimbursement from the Board on their return. Patients will only be eligible to receive reimbursement for

treatments, products and services that would normally be provided by the health service based on their clinical need. Therefore countries which wish to refuse reimbursement for services they do not normally provide will need to ensure that their patients are well informed as to their healthcare entitlements.

11.11 The health service does not have a defined list of healthcare to which all patients are entitled. Domestic legislation is instead premised on providing a comprehensive range of services within a universal healthcare system where the local commissioner i.e. the Board makes decisions on what treatments should be prioritised for the Northern Ireland population, with a clear focus on commissioning for outcomes.

11.12 The health service will therefore need to provide patients with far greater clarity as to which services it does and does not fund so as to avoid uncertainty for patients and to meet transparency requirements.

Achieving clarity on patient entitlements

11.13 In setting out the principles under which the health service should provide clarity on entitlements to patients, the Department proposes placing in the implementing legislation a broad legal requirement on the Board to provide information to patients on their rights and entitlements in relation to receiving cross-border healthcare, in accordance with Directions made by the Department. The regulatory measure would set the basic legal framework for the Board and associated Directions would set the detail of how the requirement should be met, including:

- the information to be provided, (this would need to include published information on services that are or are not generally available to health service patients, including clinical and other access thresholds);
- the form in which the information is to be provided;
- the time limits by which it should be made available;
- training requirements for staff dealing with queries, and

- any other matter necessary to ensure they carry out this function appropriately.

11.14 The Board in the information it publishes for patients could also provide information about how patients can get further information including details of whom to contact. However, patients cannot be compelled to have further discussions with any contact point (although patients would be recommended to do so).

11.15 Where the Board has a policy on a treatment or service, it 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.

11.16 It is proposed that the Board will act as a contact point for patients who cannot ascertain whether or not a treatment is available through the health service. The Directions will cover what is specifically required, and it is proposed from the outset to do enough to ensure that patients can get the information they need easily without requiring the Board to do more than is necessary to assure this.

Consultation questions

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

If not, what additional measures should be considered to ensure that the health service is able to deliver the required clarity on entitlements and thereby respond appropriately to patient requests?

12. Article 6 – National Contact Points for cross-border healthcare

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

- provide information including the right of a specific healthcare provider to provide services and any restriction on its practice;
- provide information about 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 Reg. 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;
- co-operate with other NCPs and the Commission and provide patients with contact details of NCPs in other Member States.

12.2 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 of the Disability Discrimination Act 1995 as amended by the Disability Discrimination (Northern Ireland) Order 2006, the legislation which contains specific provisions for reasonable adjustments to be made by public bodies in respect of disabled persons.

12.3 The UK constituent territories of Scotland, Wales, Northern Ireland and Gibraltar intend to set up their own NCP arrangements and these will link together for the UK member state as a whole.

NCP in Northern Ireland

12.4 The Department has given consideration to the best location for the NCP in Northern Ireland and has concluded that due to the nature of the NCP's functions, it would be best locating the NCP within the Board. This will ensure compatibility of approach and secure the best delivery of the functions of the NCP for cross-border healthcare in Northern Ireland.

12.5 Nevertheless, it should be remembered that these are different functions. While the NCP will need good links with the prior-authorisation and reimbursement sections of the Board, it will play no role in the decision-making mechanisms under the Directive, or in making recommendations on potential providers in other countries. Its role is the provision of information to patients - ultimately, the patient will need to decide how to use the information provided.

12.6 The NCP in Northern Ireland will need to be formally established via the implementing legislation. Additionally, as part of the implementing regulations, it will be more convenient for the reader if the responsibilities on NCPs, which are set out variously at Articles 4, 6 and 10, are grouped together in the Regulations.

Consultation questions

3. Do you agree that the Board is best placed to provide the NCP function for Northern Ireland?
4. 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?
5. What might be the impact of providing clear and transparent information on the volume of patients who may wish to access cross-border healthcare?

Article 7 – General principles for reimbursement of costs

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

13.2 Article 7(2) (a) does not apply to the UK. The derogation at Art.7 (2) (b) is a minor but complex adjustment in entitlements for pensioners residing in another Member State and is relevant to Northern Ireland as well as the other UK countries. This essentially applies where the UK is what is termed the "Competent Member State" for a person in receipt of a pension (or a member of their family), who resides in another Member State; for example, a person receiving the UK state retirement pension who has retired to another Member State to live.

13.3 Broadly, when such an individual returns to the Competent Member State for a visit, then any healthcare obtained during a trip back (which is not subject to prior authorisation) shall be provided at the expense of the Competent Member State. As discussed further in this consultation, services which are likely to fall within the non-prior authorisation category will be primary care services and other diagnostic community based services. In terms of Northern Ireland, this will mean that persons receiving UK state pension and permanently residing in the Republic of Ireland may return to Northern Ireland to access these types of services for free. This would be a change from the present position where such persons can only have free immediately, necessary care when visiting Northern Ireland. "Pension" in this context includes the state retirement pension and also any long-term contribution-based social security allowance, such as Incapacity Benefit. This adjustment would be reflected in the implementing legislation.

13.4 Returning to the broader provisions of Article 7, a patient can seek reimbursement for cross-border healthcare from their home state if the same or equivalent treatment or service would have been made available to the patient by the home state.

13.5 This means that a patient who is entitled to healthcare in Northern Ireland can seek reimbursement for treatment obtained in another Member State if the service here would have provided the patient with the equivalent treatment. However, if the treatment would not be provided by the health service 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. In terms of Northern Ireland this means that reimbursable treatments will only be those which the Board commissions

routinely, subject to the usual consideration of individual exceptional cases. 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.

13.6 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 legislation made by the Department in 2012, which enables reimbursement to be capped at the equivalent Northern Ireland health service cost.

13.7 Nevertheless, under Article 7(6), Member States must also have a transparent mechanism for the calculation of costs of cross-border healthcare that will be reimbursed. Any calculation must be based on objective and non-discriminatory criteria known in advance.

13.8 Under Article 7(9), Member States may restrict reimbursement for overriding reasons of general interest if the demand for cross-border healthcare for 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, it would be necessary to show that such a restriction was proportionate and not discriminatory. Given the requirements under other parts of the Directive on Member States to collect information, it is likely that any high level of demand would become apparent relatively quickly.

What to reimburse

13.9 The current mechanisms for reimbursing patients in Northern Ireland are operated by the Board. Across all four UK countries, reimbursement regulations are in place at present, 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 health service treatment.

13.10 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 health service cost will be dealt with separately by administrative measures but the Directive requires Member State authorities to be able to explain the reimbursement calculation and be able to justify it to applicants.

13.11 The Department currently compiles annual schedules showing unit costs for approximately £900m of inpatient and day case expenditure, covering almost all acute care provided in these settings. Although there is no tariff system in Northern Ireland, these unit costs are compiled on the same Healthcare Resource Group basis that forms the basis of the national tariff system in the NHS in England. In addition, unit costs are compiled for a further approx. £300m of outpatient care and £1.4bn of community care. Together these unit costs cover around 88% of all care provided by health service trusts in NI.

13.12 In principle, the Department proposes that reimbursement would be limited to the relevant average HRG or other unit cost for Northern Ireland, where such an average is not available, reimbursement may be on the basis of the relevant English, Scottish or Welsh NHS cost, if available. Where there is no NI or other UK equivalent unit costs or price available, and it would not be practical or possible to develop such a cost within the time limits, the Department may have to reimburse the actual cost of treatment.

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

Calculating reimbursable costs

13.15 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 health service and then compare this to the invoices and receipts. If the actual amounts paid for treatment in Europe were lower than the health service costs in Northern Ireland, then the reimbursable amount is limited to the actual amounts paid (adjusted to take account of any

deductible health service charges in accordance with Article 14B of the Health and Personal Social Services NI Order 1972). If the actual amounts paid were greater than the calculated health service cost (adjusted to take account of any deductible charges, etc.), then the calculated health service cost is the maximum amount that may be reimbursed, in accordance with existing statutory provision.

Consolidation of Cross Border Healthcare functions in the Board

13.16 For patients, there is a clear need to ensure that the process for determining entitlements and making decisions on prior authorisation and reimbursement is sufficiently transparent and timely. Those from the health service involved in administering the reimbursement provisions must have a full understanding of the legal requirements placed upon them. The Department in 2012 when making the interim regulations decided to place the functions of prior-authorisation and reimbursement with the Board given its key role as Commissioner in Northern Ireland. In implementing the Directive it is proposed to consolidate this position and place the cross border healthcare functions with the Board. The Department believes this will ensure critical mass of expertise and consistency in decision making and application of the law.

13.17 Following implementation of the Directive the Board would have the following functions:

- receiving patient applications for authorisation under Regulation 883/2004 and reimbursement under Article 14B of the HPSS Order 1972 (the Article 56 provisions);
- reimbursing patients their eligible costs;
- considering applications for prior authorisation;
- granting or refusing prior authorisation;
- calculating reimbursement levels and informing patients about this;
- dealing with appeals & reviews;

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

Relationships with Health and Social Care Trusts and GP Practices

13.18 The function of deciding as to whether or not a patient should be reimbursed for accessing services in Europe under the various provisions of the directive is a complex and technical area. As a result, the Department considers that it would be in the interests of patients for cross border healthcare to be managed by experts efficiently via the Board alone.

13.19 However, this does not mean that Health and Social Care Trusts and GP practices do not have an important part to play in terms of cross border healthcare and it will be essential for good links to be maintained, particularly to ensure clear information is available to patients about their entitlements and to enable swift determination in cases where prior authorisation is a consideration for access to cross-border healthcare.

13.20 Most people prefer to be treated close to home, however, the Department is increasingly aware of growing interest in the potential use by patients of their rights to access treatment in other EEA states. The Directive provides a means for enabling patients to make choices, which go beyond traditional borders. The system needs to be proactive and not defensive when responding efficiently to such requests. It is essential that the relevant parties in the system work together to the benefit of patients.

Equity

13.21 One of the most evident potential inequalities arising from the Directive is the requirement that patients must pay in advance for their healthcare treatment within the EEA and then claim a reimbursement of eligible costs upon their return home. This clearly has the potential to exclude from accessing cross-border treatment those without the necessary financial resources.

13.22 For this reason, and building on the existing discretion afforded to the Board in its role as Commissioner, the Department believes that it would be appropriate for the Board to be able to make payment directly to overseas providers on behalf of the patient following treatment, in effect acting as a third party, since this is allowable under the Directive. However, it is critical in allowing this that the Board does not invoke the health service duty of care, as the Board will never be formally commissioning the treatment - it will simply be assisting the patient in exercising their individual rights.

13.23 This would not be the normal arrangement of preference under the Directive; the general expectation would be that most patients would pay the provider directly at the point of treatment and then seek reimbursement on return home. However, the Department believes that this is a discretion that should be available to the Board in exceptional cases 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 to the Board acting as a third party and being in no way liable for the outcome of treatment.

Consultation questions

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

13.24 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 domestic legislation. The Directive does not therefore create any new entitlements in these areas.

13.25 In Northern Ireland (as is the case in the other UK countries) there are 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 Northern Ireland, 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.

14. Article 8 – Healthcare that may be subject to prior authorisation

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

authorisation be used to discriminate against patients or place an obstacle to the exercise of rights under this Directive.

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

14.3 Currently, patients in Northern Ireland seeking treatment in another EEA Member State are required to contact the Board in advance of travelling to discuss whether prior authorisation is required, as well as what levels of cost reimbursement will apply. This should happen before the patient accesses treatment in another Member State, though retrospective applications may also be considered. Under Article 8(7) of the Directive, the Board will have to publish clear information to patients as to which services come within the scope of prior authorisation and what the process is for applying for it are. While patients will be advised to have a conversation with health experts at home before they travel, they cannot be obligated to do so.

14.4 This process of authorisation enables the patient to confirm that they are entitled to the treatment requested, as well as the level of reimbursement they can expect. It also allows the Board to ensure that patients are aware of all of the possible treatment options within the health service in Northern Ireland, 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 right to seek treatment in Europe are entitled to do so and to apply for reimbursement subject to the conditions and limits set out in legislation. Under existing legislation, reimbursement for certain types of specialised or cost intensive services are subject to a requirement that the patient has obtained prior authorisation. Authorisation must also be granted where the health service cannot provide the treatment without undue delay.

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

14.6 Where a Member State decides to adopt a system of prior authorisation, the categories of healthcare to which the condition applies must satisfy the criteria set out in Article 8(2), namely:

(a) healthcare is made subject to planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, so far as possible, any waste of financial, technical and human resources and:

(i) involves overnight hospital accommodation of the patient in question for at least one night; (e.g. specialist or some planned surgery) or

(ii) requires use of highly specialised and cost-intensive medical infrastructure or medical equipment, (examples here might be expensive diagnostic services, PET CT, MRI scans etc.);

(b) involves treatments presenting a particular risk for the patient or the population, (could include any treatment using e.g. radioactive isotopes); or

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

14.7 The categories of healthcare selected by the Member State must be notified to the Commission and be made publicly available. It will be necessary to have robust evidence demonstrating that the categories of healthcare satisfy the criteria. Under current domestic legislation, in Articles 14A and 14B of the HPSS Order 1972 the right to reimbursement of the cost of some healthcare, defined as a “special service” is subject to the condition of prior authorisation. The definition of a “special service” will need to be replaced to reflect the criteria set out above. The categories of

healthcare to which a system of prior authorisation might apply are discussed at paragraph 6.120 below.

Discretion to refuse prior authorisation in certain cases

14.8 If it is finally decided to continue a system of prior authorisation, refusal of authorisation is only permitted in four circumstances, which are set out in Article 8(6):

(a) Where the patient will, according to a clinical evaluation, be exposed with reasonable certainty to a patient-safety risk that cannot be regarded as acceptable, taking into account the potential benefit for the patient of the sought cross-border healthcare, (this could be from poor quality care or unproven procedures);

(b) where the general public will be exposed with reasonable certainty to a substantial safety hazard as a result of the cross-border healthcare in question, (this might include where a patient who had a highly contagious disease wanted to go to another state for treatment or where a patient with mental health problems and a history of violence requested authorisation);

(c) where this healthcare is to be provided by a healthcare provider that raises serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety, including provisions on supervision, whether these standards and guidelines are laid down by laws and regulations or through accreditation systems established by the Member State of treatment, (this would require evidence from the appropriate regulator or authority);

(d) Where this healthcare can be provided on its territory within a time-limit which is medically justifiable, taking into account the current state of health and the probable course of the illness of each person concerned.

14.9 The criteria (a), (b) and (c) above are relatively straightforward and uncontroversial, although they are really only seen as exceptional measures. For (c) in particular, it is unlikely that this would ever be useable because it would require health systems

to have defensible evidence about a lack of robust service regulation and quality failures by a provider in order to avoid challenge.

14.10 Criterion (d) above can be summed up as "where there is no undue delay". It essentially means that reimbursement of the cost of cross-border healthcare may be refused where the health service is able to deliver the healthcare to the patient in a medically justified time period based on a clinical assessment of the individual patient's condition and not merely by reference to a general waiting time.

14.11 The ECJ, in previous cases (notably in Watts vs. Bedford PCT) has said that refusal of prior authorisation is permitted where treatment can be provided within the home system in these circumstances. There is no doubt that in some instances the Board may find it helpful to utilise this provision when treatment can be provided without delay as a way of limiting reimbursement expenditure. However, the Directive is clear that the use of the criteria is restricted and cannot be used as an unjustified obstacle to the free movement of patients. The Court of Justice has also confirmed that the unjustified use of systems of prior authorisation constitutes a barrier to freedom of movement and is contrary to European law.

14.12 Essentially, the Directive starts from the premise that the use of systems of prior authorisation is to be restricted to what is necessary and proportionate. The operation of a system of prior authorisation in accordance with the Directive should be seen as a two stage process.

- The first stage is to identify those categories of healthcare which satisfy the criteria in Article 8(2) – i.e. subject to prior authorisation;
- The second stage is to ensure that if the discretion to refuse authorisation where the health service can provide the equivalent treatment "without undue delay" is adopted, then that discretion is operated correctly, in a proportionate manner and not in a way that undermines the purpose of the Directive.

14.13 The European Commission has indicated that it will be looking carefully at how both Article 8(2) and Article 8(6), particularly 8(6)(d) are adopted by Member States, in order to ensure the provisions are not used as a blanket restriction on patients' rights.

14.14 Research commissioned by the Department of Health in England, and in which the Department in Northern Ireland participated, conducted over 2009/10 (by the Health Economics Consortium at the University of York) concluded that many NHS commissioners lacked understanding and clarity about patient rights under EU law and their entitlement to reimbursement. In terms of Northern Ireland, the Department considers that the earlier decision to centralise cross border healthcare matters in the Board and to consolidate this position following implementation of the Directive in October 2013 will undoubtedly help to ensure that future decision making is based on sound expertise in this complex area. Nevertheless, it is recognised that there is a need to ensure that restricted criteria for the refusal of prior authorisation are not used disproportionately.

14.15 As identified above, in Northern Ireland, it is felt that consolidation of the position of cross border healthcare within the Board alone will ensure clearer administrative processes as well as consistency of the application of the rules in such cases. However, to assist with this aim, the Department is of the view that where applications for prior-authorisation are refused, the Board should be clear about why a particular decision has been made.

14.16 In particular, where the criterion of "where there is no undue delay" is used to justify refusal of authorisation, it will be necessary for the decision to set out in full the reasons, explaining why the decision maker concluded that the health service could provide the treatment within a medically justifiable period of time, based on an individual assessment of the patient's case. The Department anticipates that in justifying the use of this criterion, the health service would also be expected in each individual case to specify in writing the medically justified period of time during which treatment must be provided, based on an assessment of the individual patient and what would constitute undue delay for that patient. The ECJ has been clear that "undue delay" cannot be determined simply on the basis of general waiting time arrangements.

14.17 Nevertheless, the Department acknowledges that providing this level of evidence on an individual, case-by-case basis would be burdensome on both clinicians and the Board, so there is a need to consider carefully the extent to which this criterion is used, if at all.

Options

14.18 This is a complex measure and it is recognised that there will be legitimate interests within the health service and beyond on how (or whether) Art.8 (6) (d) should be taken forward. Therefore, this consultation seeks views on the issue, with three potential options as follows:

Option 1

Adopt Article 8(6) (d) without limit

14.19 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, the Department has serious concerns that adoption without limit would lead to a tendency to ignore the restrictions in order to limit the number of patients seeking to access their rights in line with waiting times at home.

14.20 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, it must be considered whether it is a necessary and proportionate approach, given that there are only presently small numbers of patients using their rights under EU law.

14.21 If the need for a restriction is because of a sudden and growing demand from patients for particular services, the health service could seek to use the powers available at Art.7(9). This allows, in certain circumstances, and where evidence is available, a Member State to limit access to cross-border healthcare for overriding reasons of general interest.

Option 2

Adopt Article 8(6) (d) but only to services for which an individual funding request would normally be made to the Board in accordance with its protocol on individual funding requests and extra contractual referrals available at;
http://www.hscbusiness.hscni.net/pdf/Protocol_ECR_and__IFR_arrangements.pdf

14.22 This will hopefully lead to a proportionate approach being taken towards all requests for cross border healthcare. This option limits the administrative burden on the health service and the restrictions on an individual patient's freedom to choose to obtain healthcare in another Member State and claim a reimbursement.

14.23 As described above, the health service would also need to set out for each patient it refused, exactly what would, from a medical standpoint, represent "undue delay" in their individual case. This would be in order to avoid patients being refused authorisation but being forced to wait longer than medically necessary for treatment at home. The list of services subject to prior authorisation and the restrictions that apply would need to be developed and agreed, with the same safeguards applied as with option [i]. In providing evidence of the proportionality of refusal, the health service would need to do the following:

- consider the patient's medical history;
- consider the extent of any pain, disability, discomfort or suffering that is attributable to the medical condition to which the service relates to;
- whether any such pain, disability, discomfort or suffering makes it impossible or extremely difficult for the patient to carry out ordinary daily tasks;
- the extent to which the provision of the service would be likely to alleviate, or enable the alleviation of pain, disability, discomfort or suffering; and
- set out what is the medically necessary time limit within which the treatment that the patient needs should be carried out (NB – this is not to be confused with

waiting time limits or averages within the system which may not be appropriate in the context of the individual circumstances of the patient.)

Option 3

Do not adopt Article 8(6)(d)

14.24 This preserves the central ethos of freedom of movement of EU citizens, which underpins this Directive. It would ensure that there was limited administrative risk of the health service imposing unreasonable restrictions on patients, which would constitute obstacles to the freedom of movement of patients. If patient demand were ever to become higher than anticipated (so that it destabilises the system), consideration could then be given to use of the powers available at Art.7 (9).

14.25 The Department's view is that either ii or iii would be the preferred options.

14.26 If option [i] were adopted, the Department is doubtful whether in practice it would be operated satisfactorily with each decision taken on the basis of the individual patient's clinical needs and in a proportionate manner bearing in mind the overall purpose of the Directive to facilitate a patient's right to obtain healthcare in another Member State. However, in order to formulate a final view the Department would welcome your views on the three options.

Consultation questions

9. Do you have a view on whether or how the Department should adopt the Art.8 (6) (d) derogation?
10. Should the derogation (if taken) be limited to those services for which individual funding requests would normally be made?
11. Do you believe this Article can be made to work in practice without being unduly burdensome?

Categories of treatments subject to prior authorisation

14.27 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.

14.28 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.

14.29 The Department takes the view that prior authorisation will not be applicable generally to services such as primary care, dentistry and ophthalmology. Equally, the Department does 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 health service. 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 health service, in the majority of cases, to demonstrate through evidence that these services meet the requirements of the criteria in options (i) and (ii) as set out above.

Individual Funding Requests

14.30 Although the Board has responsibility for commissioning health services, usually done through Health and Social Care Trusts, there are different arrangements for commissioning to providers in other parts of the UK or alternatively to providers in the Republic of Ireland for certain specialised services not available in Northern Ireland. Generally, because these are services that are very costly to provide, require high levels of skill and training, long term investment in infrastructure and medical equipment and often the setting up of dedicated teams and specific contract arrangements to be made that require a certain amount of pre-planning and patient numbers to make their provision viable, it makes sense for these to be prior-authorisation treatments. However, there may be other treatments and

interventions, which require significant levels of health system planning or cost-intensive medical infrastructure that may potentially need to be included in the list of categories of "treatments subject to prior authorisation". For example, complex diagnostics and imaging services (MRI etc), which can cost millions of pounds in capital set up costs, training and so on. The Department welcomes views on other such services that might be included in the categories of treatments subject to prior authorisation.

Consultation questions

12. Do you agree that Northern Ireland should continue to operate a system of prior authorisation for patients requiring certain types of treatment?
13. In addition to those services typically requiring individual funding requests and services such as diagnostics requiring considerable planning and financing what other services might come within the scope of treatments/services that should be subject to prior authorisation?
14. What is the evidence to support this inclusion?

Interaction with Regulation (EC) No 883/2004

14.31 Significantly, Art.8 (3) states that when a patient requests prior authorisation for a relevant treatment, the home state must first of all determine whether or not the patient meets the requirements of Regulation 883/2004 (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 abroad.

14.32 The Board will consider the relevant aspects of both the Regulation and Directive routes and concentration of this role within the Board will ensure that appropriate consideration occurs of patients rights under both sets of legislation and that the relevant case law is applied effectively. This provision will need to be reflected in the implementing regulations, and backed up by guidance.

Rare diseases

14.33 Finally, Art.8 (4) states that if a patient is suspected of having a rare disease and applies for authorisation, the home state may carry out a clinical evaluation by experts. If there are no experts in the rare disease in question in the home system, or the expert's opinion is inconclusive, the home state may request scientific advice of experts in another State. This clause reflects the EU Parliament's and Commission's growing interest in seeking to advance the rights of citizens suffering with rare disease in particular (rare disease is defined as a prevalence of 5:10,000). However, this is discretionary and not a binding obligation and as such does not require specific provision in the implementing legislation.

15. Article 9 – Administrative procedures regarding cross-border healthcare

15.1 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. The Department proposes replicating in the implementing regulations the current legislative provision of 20 working days for the decision making process, unless further information is required. As with current arrangements, decisions on requests must be challengeable, both by administrative review and judicial proceedings.

15.2 It is further proposed to include in the guidance accompanying the implementing regulations a section entitled "general principles", to capture the way in which healthcare providers in Northern Ireland 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.

15.3 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 to use the existing mechanisms under the Regulation for the payment of costs incurred by patients under the Directive.

15.4 There is a benefit for patients to have a dialogue with the Board about entitlement and reimbursement levels, and patients are encouraged to do so, but this is with the realisation that any mandatory requirement to do so is likely to be disproportionate and overly bureaucratic. However, there may be some merit in a voluntary system, operated by the Board, which encourages the correct dialogue to take place between patient and the Board in advance of treatment not subject to mandatory prior authorisation and the Department welcomes views on this issue.

Consultation questions

15. Is the current decision making timescale of 20 days reasonable, or should it be amended?
16. 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?
17. What would such a system look like and how could it work in practice?

16. Article 10 – Mutual assistance and co-operation

16.1 This Article needs to be read, and implemented, in conjunction with Articles 4 and 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.

16.2 The Member State of treatment must, on request from the authorities of other Member States make information available about the right of health professionals to

practice in their territory. This would require professional regulators to share the registration status of health professionals when requested through the Commission Internal Market Information (IMI) system. This is now obligatory for this Directive and all competent authorities that would be exchanging such information should be using the IMI system.

16.3 Moreover, while the Department believes 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 subject to disciplinary/court action etc. We welcome the views of respondents to this consultation.

Consultation question

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

17. Article 11 – Recognition of prescriptions issued in another Member State

17.1 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 Northern Ireland GP could write a prescription that would be dispensed in another EU Member State for continuity of care purposes. However, it does not affect any national rules that States have for prescribing and dispensing, particularly ethical rules, e.g. for the right of pharmacists to refuse to dispense had the prescription been issued in the home system.

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

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

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

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

17.4 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 Art.11 aims to achieve, pharmacists can currently dispense prescriptions written by doctors and dentists lawfully practising medicine or dentistry in another EEA State or Switzerland, provided certain conditions are met. The decision to accept the prescription is subject to the professional judgement of the pharmacist.

17.5 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. The new non-exhaustive list, attached at annex B, 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.

17.6 MHRA and the Department of Health England will be taking forward these amendments to the medicines legislation to adopt the non-exhaustive list for both incoming and outgoing cross-border prescriptions. The Department considers that this will benefit patient safety and offer more certainty for the dispensing pharmacist. Critically, 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

17.7 During negotiations on the cross-border Directive it was established that the controlled drugs exclusion under current domestic regulations will come within the scope of medicinal products subject to special medical prescription (SMP) under Art.11(6).

17.8 Under European and domestic legislation, unless they are exempted by legislation, medicinal products require a marketing authorisation under which the product is classified as one which is either available only on prescription (POM) or is available without a prescription. Although the relevant governing Directive (2001/83/EC) allows Member States to designate certain types of SMP products as a sub-category of POM, this designation has never been made in UK legislation because the requirement is not mandatory, and in the Government's opinion, no compelling need to make such a designation was identified.

17.9 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.

17.10 The changes will be implemented by way of an amending Statutory Rule 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 MHRA lead and the provisions are governed by the Medicines Act 1968, as amended, which is UK-wide in scope. Provisions are in place in domestic legislation that provide much of what Art.11 aims to achieve, where they are not, separate implementing legislation will be prepared by the MHRA. The Agency does not envisage that the adoption of the SMP category into UK law will impact on stakeholders as any practical effects will fall on its internal administrative processes.

18. Article 12 – European reference networks

18.1 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 the Member States, and might work to improve access to diagnosis and the provision of high-quality healthcare to all patients who have conditions requiring a particular concentration of resources or expertise.

18.2 Participation is voluntary, albeit expected and encouraged and as with Art.8 (4), the Commission's key focus of attention is advancing the agenda on rare disease. Art.12 sets out the criteria for the establishment of a network to include:

- European co-operation 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.

18.3 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.

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

19. Article 13 – Rare diseases

19.1 Article 13 was a late addition to the Directive to strengthen the message on pan-European co-operation and treatment of rare diseases. 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.

20. Article 14 – eHealth

20.1 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 eHealth agenda for the transmission of data in cross-border care. Article 14 sets out that the objectives of the network will be:

- to work towards interoperability of e-Health systems and services;
- to draw up guidelines on patient summaries' data to be shared across borders;

- identify effective methods for enabling the use of medical information for public health and research;
- develop common identification and authentication measures to facilitate cross-border healthcare.

20.2 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 the 8 May 2012 in Copenhagen. Measures adopted shall not interfere with Member States' competence in implementing eHealth systems or harmonise national laws, so are not mandatory.

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

21. Article 15 – Co-operation on Health Technology Assessment (HTA)

21.1 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 'EUnetHTA', more information about EUnetHTA can be accessed through the website: www.eunethta.eu. Two UK partners are active participants in this work, the NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC) and the National Institute for Health and Clinical Excellence (NICE).

21.2 The Department of Health supports international collaboration in HTA and welcomes the Commission's support for ongoing voluntary co-operation in this area. However, decisions about which treatments to provide, including the assessment of new medicines and technologies, clearly form part of Member State's responsibilities in the organisation, financing and management of national health systems. Different

systems use health technology assessment in different ways and EU initiatives in this area, including the voluntary network, must reflect this. In particular, it is important to be clear that the UK is not working towards the creation of a single EU HTA body.

21.3 The Department of Health believes that sharing of information and methods, and streamlining of information requirements are likely to be the most valuable and productive areas for continuing cooperation in HTA at EU level. The Department will be involved in the development of the voluntary European network on HTA alongside the other three UK health departments. 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.

21.4 The Commission 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

22. Articles 16-19 - Committee & delegated acts

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

23. Article 20 – Reports

23.1 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.

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

23.3 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 the Department anticipates will need to be built in to the responsibilities of the National Contact Points based in the Board (Art.6). The Department understands that the European Commission intends specifying a range of data and information requirements about the uptake and use of the Directive, which Member States will be asked to collect.

23.4 in Northern Ireland, this may be a role that the Board leads on or at the very least inputs to and it may therefore be necessary to set down in directions to the Board how this data is to be collated.

24. Article 21 – Transposition

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

Annex A

The Health Regulators and Professions Regulated

Health professional regulator	Regulated health profession
General Chiropractic Council	Chiropractors
General Dental Council	Dentists Dental hygienists Dental therapists Clinical dental technicians Orthodontic therapists Dental nurses Dental technicians
General Medical Council	Doctors
General Optical Council	Dispensing opticians Optometrists
General Osteopathic Council	Osteopaths
General Pharmaceutical Council	Pharmacists Pharmacy technicians
Health Professions Council	Arts therapists Biomedical scientists Chiropodists Clinical scientists Dieticians Hearing aid dispensers Occupational therapists Operating department practitioners Orthoptists Orthotists Paramedics Physiotherapists Podiatrists

	Practitioner psychologists Prosthetists Radiographers Speech and language therapists
Nursing and Midwifery Council	Nurses Midwives
Pharmaceutical Society of Northern Ireland	Pharmacists

Annex B

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

Identification of the patient

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

Authentication of the prescription

- Issue date.

Identification of the prescribing health professional

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

Identification of the prescribed product, where applicable

- Common name as defined by Article 1 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2011 on the Community code relating to medicinal products for human use;
- The brand name if:
  (a) the prescribed product is a biological medicinal product; or

(b) the prescribing health professional deems it medically necessary; in that case, the prescription shall shortly state the reasons justifying the use of the brand name;

- Pharmaceutical formulation (tablet, solution, etc.);
- Quantity;
- Strength, as defined in Article 1 of Directive 2001/83/EC;
- Dosage regimen.

Annex C

Summary of questions for stakeholders

General

1. What proportionate measures can the Department 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 Northern Ireland patients as well as the impacts this has on the HSC (budget, administrative costs, commissioning etc).

Responsibilities of Member State of treatment (pages 16 - 30)

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

Responsibilities of Member State of affiliation (pages 30 - 34)

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

National Contact Points (pages 34 - 36)

6. Do you agree that the Board is best placed to deliver the NCP function for Northern Ireland?

7. What information, and presented in what format(s), do you think patients need to make an informed decision on receiving treatment in another EU Member State?

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

9. What do you think about the Department's approach to implementing the Directive into primary care services in Northern Ireland including GP, dental and pharmacy services?

10. Can you suggest how the system might be able to assess and treat patients under the Directive in primary care settings?

11. Do you have any concerns or issues that you wish to highlight in terms of access to primary care services by patients under the Directive?

12. What types of mechanisms such as monitoring and supervision systems would you like to see in primary care?

General principles for reimbursement of costs (pages 36 - 42)

13. Do you agree that the Board should have discretion to make payments direct to overseas providers, where this would be beneficial for patients with limited financial means?

14. If so, what safeguards would you like to see put in place?

15. How might any adverse impact be managed?

Healthcare that may be subject to prior authorisation (pages 42 - 53)

16. Do you agree that Northern Ireland should continue to operate a system of prior authorisation for patients requiring certain types of treatment?

17. In addition to specially commissioned services by the Board (from other providers than HSC Trusts) 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?

18. What is the evidence to support this inclusion?

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

20. Should the derogation (if taken) be limited to the types of services for which the Board normally conducts arrangements outside Northern Ireland such as to providers in England

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

Administrative procedures (pages 53 - 54)

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

23. 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?

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

Mutual assistance and cooperation (pages 54 - 55)

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

Section 75 and equality

Section 75 of the Northern Ireland Act 1998 requires each public authority, in carrying out its functions in relation to Northern Ireland, to have due regard to the need to promote equality of opportunity. The Department has conducted a preliminary screening of the proposals to implement the EU Cross Border Healthcare Directive in Northern Ireland and in light of this screening exercise has concluded that a full Equality Impact Assessment of these proposals is not required. The preliminary screening is also available online at: www.dhsspsni.gov.uk/index/consultations/current_consultations.htm

26. Are the proposals set out in this consultation document likely to have an adverse impact on any of the nine equality groups identified under Section 75 of the Northern Ireland Act 1998?

27. Are you aware of any indication or evidence, qualitative or quantitative, that the proposals set out in this consultation document may have an adverse impact on equality of opportunity or on good relations?

28. Are you aware of any further impact on healthcare professionals or patients as a result of the proposals?

29. Is there an opportunity to better promote equality of opportunity or good relations?

30. Are there any aspects of these proposals where potential human rights violations may occur?

Annex D

Circulation of proposals and consultation responses

1. A copy of this document and attachments is also available at: www.dhsspsni.gov.uk/index/consultations/current_consultations.htm

2. If you require a copy of this consultation paper in any other format, e.g. braille, large font, audio, please contact the address below.

Responding to this consultation

3. The Department would welcome your views on the proposals set out in this document. Please use the questions contained at annex C as a guide to forming your response.

Hard copy replies should be sent to:

Robert Kirkwood

Primary Care Medical Services Branch

Room D3.20

Castle Buildings

Stormont Estate

Belfast

BT4 3SQ

Replies can be sent by fax to 028 90 765 621

Email replies should be sent to: eucrossborder@dhsspsni.gov.uk

Telephone enquiries about this consultation can be made to 02890 520245

4. Replies should reach the Department by 13 September 2013.

5. A summary of responses may be published in conjunction with any further action.

Annex E

Freedom of Information Act 2000: Confidentiality of Consultations

1. The Department may publish a summary of responses following completion of the consultation process. Your response and all other responses to the consultation may be disclosed in full on request. The Department can only refuse to disclose information in exceptional circumstances. Before submitting your response please read the paragraphs below.

2. The Freedom of Information Act gives the public a right of access to any information held by a public authority, namely the Department in this case. This right of access to information includes information provided in response to a consultation. The Department cannot automatically consider as confidential information supplied to it in response to a consultation. However, it does have the responsibility to decide whether any information provided by you in response to this consultation including information about your identity should be made public or be treated as confidential.

3. This means that information provided by you in response to the consultation is unlikely to be treated as confidential except in very particular circumstances. The Lord Chancellor's Code of Practice on the Freedom of Information Act provides that:

(a) the Department should only accept information from third parties in confidence if it is necessary to obtain that information in connection with the exercise of any of the Department's functions and it would not otherwise be provided;

(b) the Department should not agree to hold information received from third parties "in confidence" which is not confidential in nature, and

(c) acceptance by the Department of confidentiality provisions must be for good reasons, capable of being justified to the Information Commissioner.

4. For further information about confidentiality of responses please contact the Information Commissioner's Office or visit:

www.informationcommissioner.gov.uk.

Annex F

Glossary of Terms

Board	Health and Social Care Board
Department	Department of Health, Social Services and Public Safety
DH	Department of Health
ECJ	European Court of Justice
EEA	European Economic Area
EHIC	European Health Insurance Card
EU	European Union
Member state of treatment	The Member State of treatment organises and provides the healthcare. They are responsible for ensuring the quality and safety of the healthcare provided, in particular by implementing control mechanisms. They also ensure the protection of personal data and equal treatment for patients who are not nationals of their country. The NCP in the Member State of treatment shall provide patients with the necessary information.
Member State of affiliation	Following the provision of care, it is the Member State of affiliation who takes care of the reimbursement of the insured person on the condition that the treatment received is provided for under reimbursable care in their national legislation.
NCP	National Contact Point
S2	The S2 route entitles you to state funded treatment in another EEA country or Switzerland. Treatment will be provided under the same conditions of care and payment as for residents of that country.

Transposition	Much of European law takes the form of Directives setting out broad principles and objectives but leaving Member States the choice of methods to implement them. For instance, Member States may invite the private sector to set up voluntary schemes to reach the objectives, yet often this involves the transposition of the Directive into national or regional legislation. Member States have to reach the objectives within a given time period. The Commission monitors that the transposition is timely and correctly done, so as to attain the results intended by the EU policy.

Annex G

CONSULTATION LIST

All Northern Ireland Party Leaders

Other Northern Ireland Parties

MPS and MEPs who are not Party Leaders or MLAs

MLAs

Speaker NI Assembly

Committee for Health, Social Services and Public Safety Members

Assembly Business Office

Assembly Library

OFMDFM, Machinery of Government Division

OFMDFM, Central Management Unit

Northern Ireland Office – Devolution and Legislation Division

NSMC -NI

Legal Deposit Libraries

Departmental Library

Chief Executive – Health and Social Care Board

Chief Executive – Business Services Organisation

Chief Executives – Trusts

Chief Executive – NI Social Care Council

Chief Executives of Health and Social Services Councils

BMA

Royal College of General Practitioners (NI)

General Practitioners Committee (NI)

General Medical Council (NI)

BDA

Pharmaceutical Society of NI

Community Pharmacy NI

NI Optometric Society

Association of Optometrists UK

Patient Client Council

Royal College of Midwives

National Clinical Assessment Authority (NI)

Community Relations Council

Disability Action

Information Commissioners Office

Confederation of British Industry – NI Branch

Federation of Small Businesses

NI Chamber of Trade

NI Council for Voluntary Action

Chief Constable PSNI

Food Standards Agency

NI Local Government Association

Ministry of Defence

NIACRO

NI Citizens Advice

Society of local Authority Chief Executives

The Bar Library

Law Society

Lord Chief Justice's Office

Belfast Solicitors Association

Law School - QUB and UUJ

NI Court Service

Law Centre

Civil Law Reform Division

Equality Commission

NI Ombudsman

Catholic Bishop of NI

Human Rights Commission