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STUDY

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POLICY OPTIONS FOR THE PROPOSED DIRECTIVE ON PATIENT'S RIGHTS IN CROSS-BORDER HEALTHCARE

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Introduction

1.1 Objective of this study

The objective of the study is to highlight policy options in relation to the recent proposal put forth by the European Commission for a directive on the application of patient's rights in cross-border healthcare.

The European Parliament's Committee on the Internal Market and Consumer Protection (IMCO) is preparing an opinion on the proposal for a directive. During the first exchange of views in the Committee a number of questions were raised. The objective of this study is to look into the following questions:

1. **Regulatory issues and Professional qualifications:** The proposed directive sets rules for cross border access to services regulated in different Member States and will co-exist with the existing directive on mutual recognition of professional qualifications. The following questions have emerged:
    a. What options exist to improve the proposal to ensure clarity regarding which regulator will be responsible for regulating a healthcare service in the various forms of cross border service provision covered by the directive, including those where healthcare services are provided remotely?
    b. How could the proposed directive be clarified regarding obligations for Member States to proactively share information on disciplinary issues and for systems to ensure the exchange of information on the current competency of professionals?
2. **Patient's rights and certainty:** The European Parliament has called for an instrument to increase legal certainty for patients, notably in respect of clarifying legal responsibility in cases of harm as a result of (a) healthcare services provided in another Member State than the one where the patient is insured, and (b) services provided to a Member State other than that where the provider is based or resides. What options are available to clarify the proposal regarding:
    a. Possibilities and procedures for legal action towards the responsible healthcare institution or practitioner?
    b. Responsibilities for treatment in another Member State when the patient subsequently receives follow-up treatment in the home country?
    c. Rules for the calculation of compensation in cases of maltreatment? **Demography of healthcare professionals:** There are some fears that the proposal will result in unbalance in the geographical distribution of healthcare professionals in the EU.
    d. What policy options are available which - without unduly hampering the free movement in the Single Market - can prevent increasing mobility from leading to a lack of professionals in certain areas?
3. **Mutual recognition of prescriptions:** The proposed directive foresees mutual recognition of prescriptions issued in other Member States.
    a. How can the proposal be clarified regarding the situation for authorities and patients in cases there a prescribed medicine is not authorised or reimbursed in the home country of the patient?

4. **European reference networks:** The proposal calls on Member States to develop European reference networks of providers of healthcare providers which should be open for new healthcare providers which might wish to join them, provided that such healthcare providers fulfil all the required conditions and criteria.

    a. What are the implications from those networks on accreditation procedures for national healthcare professional networks and what conditions and criteria could be requested to healthcare providers who want to join these networks?

2 The proposal for a directive on the application of patient's rights in cross-border healthcare

Health systems are mainly the responsibility of the Member States, but in some cases EU citizens seek healthcare in other Member States. Reasons include that healthcare in some instances may be better provided in another member state (for example, for rare conditions or specialised treatment), or if people living in border regions find that the nearest appropriate facility is situated in another country. To provide clarity and legal certainty on the cross-border healthcare as well as to support co-operation between national health systems, the Commission has proposed a directive on patient's rights in cross-border healthcare[1].

In the Services Directive[2] on cross-border services, health services are explicitly left out. Therefore, the decisions from the European Court of Justice have set the standards for cross-border healthcare. Despite several European Court of Justice rulings which have confirmed that the EU Treaty gives individual patients the right to seek healthcare in other Member States and be reimbursed at home, uncertainty remains over how to apply the principles of this legal practise more generally[3]. Moreover, the European Parliament and the Council did not feel that this approach sufficiently accounted for specificities of health services, in particular their technical complexities, sensitivity for public opinion and major support from public funds[4]. Therefore, the European Parliament and the Council have asked the Commission to propose a specific initiative on cross-border healthcare. A proposal on patient's rights in cross-border care was put forward by the Commission with the aim of providing legal certainty on this issue. In addition, the proposed Directive aims at exploiting the potential for European cooperation to help provide more efficient health care across the EU[5].

2.1 Proposal for a directive on the application of patients' rights in cross-border healthcare

As previously mentioned, healthcare was excluded from the scope of Directive 2006/123/EC on services in the internal market. The Council and the Parliament therefore asked the Commission to address issues relating to cross-border healthcare in a separate instrument. The Commission carried out an open consultation to identify the issues in the field of cross-border healthcare with contributions from Member States, regional authorities, national parliaments, national and international associations of health care stakeholders, citizens, universities and commercial organisations and companies[6]. The majority of the contributions received favoured some form of Community action on healthcare, combining both legislative elements and practical support for cooperation between European health systems. On that basis, the Commission developed the proposal for a directive on patient's rights in cross-border care. The main goals of this directive are summarised below[7].

- **Patients have the right to seek healthcare abroad and be reimbursed up to what they would have received at home.** The directive will provide clarity over how these rights can be exercised, over the limits that Member States can place on cross-border healthcare, and over the level of financial coverage provided.

[1] http://www.euractiv.com/en/health/confusion-surrounds-eu-health-services-directive/article-169882
[2] Directive 2006/123/EC on services in the internal market
[3] http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/1080&format=HTML&aged=0&language=EN&guiLanguage=en
[4] Commission of the European Communities (2008): Accompanying document to the proposal for a directive on the application of patients' rights in cross-border healthcare – Impact Assessment
[5] Commission of European Communities (2008): Proposal for a Directive of the European Parliament and the Council on the Application of Patient's Rights in Cross-border Healthcare (COM(2008) 414 final)
[6] http://ec.europa.eu/health/ph_overview/co_operation/mobility/results_open_consultation_en.htm
[7] http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/1080&format=HTML&aged=0&language=EN&guiLanguage=en

- **Member States are responsible for healthcare provided on their territory**, meaning that the quality and safety standards of the treatment they will receive in another Member State are regularly monitored and based on good medical practices.
- **The directive will facilitate European cooperation on healthcare** by supporting the development of European reference networks, which will bring together specialised centres in different Member States.
- **Health technology assessment:** The directive will help reduce overlap and duplication of efforts in this field and hence promote the effective and efficient use of resources.
- **Activities in the field of** "**e-Health**" will also be strengthened, notably by helping putting shared formats and standards that can be used between different systems and different countries in place.

2.2 Impact Assessment of the directive

While preparing the proposal for a directive on the application of patients' rights in cross-border healthcare, the Commission conducted an impact assessment to assess the impact of the different options for such an initiative. In the process, a consultation was held with a wide range of stakeholders such as individual EU citizens, health professional organisations, healthcare providers, national and regional governments, insurers, individual citizens, the industry etc., and the results of this consultation is included in the impact assessment report. Moreover, the results of the impact assessment have been discussed in an impact assessment board, and the inputs from this board have been included in the report as well.

The impact assessment focused on four options for Community action, which were as follows:

1. Baseline scenario – "do nothing". This option would leave all responsibilities to create clarity to the individual Member States
2. "Soft action": Commission would provide guidance on cross-border healthcare issues, but would not propose additional binding legal measures
3. The establishment of a general legal framework for health services in the EU through a directive on health services. This could be combined with soft actions as described above

   3A. Two parallel systems for financial aspects of cross-border healthcare (both hospital care and non-hospital care). There are currently two different routes for financial aspects of cross-border healthcare: the regulations on coordination of social security systems, and direct application of the free movement rights provided by the Treaties on the basis of the recent rulings of the Court.

   3B. Two parallel systems for financial aspects of non-hospital cross-border healthcare, hospital care through the social security regulations
4. Detailed legal rules at European level, where the Commission would propose to put in place a detailed framework of harmonising legal measures under Community law for all cross-border healthcare issues

The impact assessment analysed the economic, environmental and social impacts of the intervention and found that option 3A is the only option where the likely value of the benefits to patients outweighs the overall costs of the system. The preferred option is therefore sub-option 3A.

2.3 Draft report on the proposal for a directive from the Committee on the Environment, Public Health and Food Safety (ENVI)

The Committee on the Environment, Public Health and Food Safety (ENVI) has drafted a report on their stand on the proposal for a directive on the application of patients' rights in cross-border healthcare. The ENVI Committee stresses that the there is a definite need for the directive as the European Court of Justice (ECJ) for too long have had the role of deciding policies for patient mobility. At the same time, the ENVI Committee stresses that the ECJ judgements should not be discarded, as these judgements have been very consistent over time and thus provides a solid foundation for the directive. Another issue of great importance to the ENVI Committee is that the focus of the directive should be on patients and their rights and not so much on the mobility of healthcare professionals. At the same time, the directive should focus on patients with needs, not means, and a system of reimbursement direct from the home Member States' health authority to the receiving hospital should be put in place to remove the arguments between the patient and the hospital over payments. With respect to mutual recognition of prescriptions, the ENVI Committee finds it preferable that Member States accept drugs prescribed as part of a treatment within the cross-border health context[8].

[8] Committee on the Environment, Public Health and Food Safety (ENVI) (2008): Draft report on the proposal for a directive of the European Parliament and the Council on the application of patients' rights in cross-border healthcare

3 Policy options

3.1 Regulatory issues and professional qualifications

3.1.1 Clarification of responsibility for regulating healthcare services of cross border service provision

The proposal for a directive covers different forms of cross-border health care services. According to Recital 10, "cross-border healthcare" covers the following:

- Use of healthcare abroad (i.e.: a patient moving to a healthcare provider in another Member State for treatment); this is what is referred to as 'patient mobility';
- Cross-border provision of healthcare (i.e.: delivery of service from the territory of one Member State into the territory of another); such as telemedicine services, remote diagnosis and prescription, laboratory services;
- Permanent presence of a healthcare provider (i.e.: establishment of a healthcare provider in another Member State); and,
- Temporary presence of persons (i.e.: mobility of health professionals, for example moving temporarily to the Member State of the patient to provide services).

Article 4 (i) of the proposal for a directive states that "Member State of treatment" means the Member State on whose territory cross-border healthcare is actually provided. Further, Article 5 states that it is the Member State of treatment which is responsible for the organisation and the delivery of the treatment and for quality and safety. This is also clear from Article 11.

The "Member State of treatment" means the Member State where the patient receives treatment or, in the case of cross-border provision of healthcare, the Member State where e.g. an analysis of a sample is carried out or where an examination is carried out via telemedicine of a patient physically located in his/her country of residence. Some clarification of the proposed directive may be desirable in the latter case, since the Member State of Treatment is not explicitly defined in the case of cross-border healthcare (i.e. where healthcare services are provided remotely).

Policy option:

Expand the definition of "Member State of treatment" in Article 4 (i), stating that where healthcare services are provided remotely (cross-border), such as in the case of telemedicine services; remote diagnosis and prescription; laboratory services, the Member State of Treatment is the Member State where the healthcare professional performing the service is located.

Thus, if, say, a German patient travels to the Netherlands to receive treatment, the Dutch health authorities are responsible. If the patient remains in Germany but is diagnosed or treated via telemedicine by a doctor in the Netherlands, it is also the Dutch authorities which are responsible, and the treatment is subject to Dutch law. If, however, the patient receives treatment by a Dutch doctor on the territory of Germany, German rules apply. This is in accordance with the usual territorial principles.

This is also in accordance with the directive on the recognition of professional qualifications (2005/36/EC) [9] where the so-called host country principle is applied, meaning that a healthcare professional from Member State A wishing to pursue his profession in Member State B shall be subject to the regulations in Member State B[10]. A similar principle is applied in the Services Directive (2006/123/EC)[11].

In case telemedicine is used or a patient is referred by the German health authorities (in the Dutch/German example used above) for treatment abroad, the German health authorities and health professionals of course have a responsibility to ensure that this is prudent and in accordance with national regulations. This could perhaps be clarified in the proposed directive in order to ensure that the Member State of affiliation (the patient's home country) also has a responsibility in such situations.

3.1.2 Clarification regarding exchange of information between Member States on disciplinary issues and the competency of professionals

Another question relates to how the proposed directive could be clarified regarding obligations for Member States to proactively share information on disciplinary issues and for systems to ensure the exchange of information on the current competency of professionals.

Directive 2005/36/EC on the recognition of professional qualifications should be considered here and is also referred to several times in the proposal for a directive. The directive on mutual recognition of professional qualifications allows health authorities, when requested to recognise or issue an authorisation to a foreign health professional, to request documentation proving that the health professional in question is not barred from practising his profession in his home country and has not been convicted of any criminal offence (art. 7.2 (b) and (e). The competent authority of the host Member State may also check the professional qualifications of the service provider prior to the first provision of services (art. 7.4). Finally, Article 8 states that the competent authorities in the host Member State can require relevant information from the competent authorities of the Member State of establishment on the legality of the service provider's establishment and his good conduct, as well as the absence of any disciplinary or criminal sanctions of a professional nature

Thus, the directive on recognition of professional qualifications opens up for the *possibility* to require such information. It could be considered whether this should be strengthened in the current proposal for a directive to a *requirement,* and adding a facility at EU level (database/register) where such information can be stored and accessed by the relevant Member State authorities.

Policy options:

Include in the proposal for a directive that Member States shall inform the Commission of any disciplinary action taken against health professionals. The Commission shall set up a facility providing access to said information to competent Member State authorities upon request. This could, for instance, take the form of an addition to Article 13 (on Duty of co-operation).

[9] Directive 2005/36/EC of the European Parliament and the Council on the recognition of professional qualifications

[10] The exact text from the directive (Art. 5, § 3): Where a service provider moves, he shall be subject to professional rules of a professional, statutory or administrative nature which are directly linked to professional qualifications, such as the definition of the profession, the use of titles and serious professional malpractice which is directly and specifically linked to consumer protection and safety, as well as disciplinary provisions which are applicable in the host Member State to professionals who pursue the same profession in that Member State.

[11] Directive 2006/123/EC of the European Parliament and the Council on services in the internal market

An alternative could be to

Introduce a requirement for a health professional applying for authorisation in another Member State to produce a certificate (or an equivalent document) documenting whether any criminal or disciplinary sanctions have been taken or any cases which may result in such sanctions are pending against the health professional in question.

In connection with the latter it is, however, important to be aware of the fact that practices regarding which actions merit disciplinary (or criminal) sanction may differ between countries and that sanctions taken against a health professional in one Member State would not necessarily have been taken in another Member State, had the issue been raised there.

Exchange of information on competences and further training of professionals is not covered by the existing Directive on mutual recognition of professional qualifications. A solution could be to set up a database at European level on such competences and training provided in each Member State.

3.2 Patients' rights and certainty

The questions under this heading concern the patient's possibilities and procedures for legal action towards the responsible healthcare institution or practitioner, the responsibilities for treatment in another Member State when the patient subsequently receives follow-up treatment in the home country, and rules for the calculation of compensation in cases of maltreatment.
Regarding the possibilities and procedures for legal action, the proposal for a directive specifies that national contact points shall a.o. "help patients to protect their rights and seek appropriate redress in the event of harm caused by the use of healthcare in another Member State; the national contact point shall in particular inform patients about the options available to settle any dispute, help to identify the appropriate out-of-court settlement scheme for the specific case and help patients to monitor their dispute where necessary" (art. 12 (b)).

The NCP is required to undertake his task in "close co-operation" with other competent authorities and NCPs in other Member States and the Commission (Article 12). It could be considered whether the national contact point in the Member State where the treatment took place should be more explicitly required to assist patients from other Member States in cases where a claim for compensation or sanction is made.

Regarding the rules for the calculation of compensation in cases of maltreatment, it is not made explicit in the Directive which Member State's rules apply for compensation to the patient. This issue is further complicated by the differences in Member States' legal systems which may put the patient in a different position – better or worse in terms of whether compensation is given, and the size of compensation - than if the case concerned treatment in his Member State of affiliation. A number of options exist for clarification (choice of jurisdiction), with different impacts for patients and health care professionals.

<u>Policy options:</u>

1. *Applying the "Country of origin" principle: the applicable law is the law of the country where the service is performed (Member State of treatment)*
2. *Applying the "Country of reception" principle: the applicable law is the law of the country of the recipient of the service (Member State of affiliation)*
3. *Establishing or appointing a 3rd party (EU institution?) to evaluate, in each case, in which of the countries the claimant would be in the best position in terms of likelihood and size of compensation and decides jurisdiction accordingly*

Choosing between option 1 and option 2 is making a choice between whether the applicable law should be, roughly, that applicable to either the health professional or to the patient. From a consumer safety point of view, option 1 may be preferable, since this provides the patient with the certainty that the rules with which he may be supposed to be most familiar or have the easiest access to advice on will apply. However, it may not be applicable in practice, since health professionals would then have to operate under unfamiliar regulatory set-ups.

Establishing a third party institution, most appropriately at EU level, may create further complications and would not create certainty for the patient. Furthermore, it may prolong proceedings if a third party would have to evaluate the case in order to choose which jurisdiction should apply.

Regarding the responsibilities for treatment in another Member State when the patient subsequently receives follow-up treatment in the home country, it is important to ensure that the patient is not subjected to two national systems both dismissing the claims because it cannot be determined in which country the damage was done.

The following options can be foreseen in such a case:

Policy options:

The Member State of affiliation (home country of the patient) compensates according to national rules and may subsequently seek full or partial compensation from relevant authorities or the individual practicioner in the other MS. This would take the burden of cross-border legal action away from the patient.

Establishing a central EU fund to cover claims in case of maltreatment where both the Member State of affiliation and the Member State of treatment have supplied treatment to the patient making the claim.

3.3. Demography of healthcare professionals

3.3.1 Preventing a lack of professionals in certain areas

Some Member States (especially Newer Member States) have expressed concerns about possible "brain drain" of health professionals to other EU countries. These Member States fear that the migration of health professionals could also be seen as a signal of problems such as difficulties to attract and retain workers in the sector, lack of investment in healthcare services, or insufficient infrastructures for training and career development, leading to a destabilisation of their health systems. In the short run, language acts as a natural barrier, but this barrier is far from impenetrable. In the UK, a large proportion of hospital staff is non-British, and a large proportion of this group hails from outside the EU. Even though language barriers may be relatively small in an English-speaking country, even small language areas can overcome the language barrier. For instance, the Danish Regions in charge of Danish hospitals have recently recruited Indian doctors, providing them with an intensive crash-course in Danish.

However, other Member States and some healthcare organisations/professionals consider the health professional mobility to be more important and viable than mobility of patients. Thus, in order to fully understand the magnitude of this issue and to better assess what the possible needs and effects for a Community action is, it is advisable to first of all measure and monitor the actual mobility of healthcare professionals in Europe. If intervention is then needed in order to avoid that some Member States are significantly worse off than others, a number of policy options could be considered, which are presented below.

It should be noted that viable policy options are limited as any measure taken must not restrict the free movement of services in the Internal Market. Thus, quotas or other restrictions on the mobility of health professionals is not an option. However, a couple of "soft" policy options can be considered:

Policy Option: Code of conduct for recruiting healthcare professionals abroad

The Commission could require that Member States adopt a code of conduct for recruiting healthcare professionals, a policy option in line with the recommendations of the High Level Group and the Council decisions on ethical recruitment guidelines[12].

Only one Member State has so far adopted ethical recruitment guidelines, namely the UK, which has a code of practice for the international recruitment of healthcare professionals issued by the UK Department of Health. This code of practice identifies the guiding principles to promote high standards in the recruitment and employment of healthcare professionals from overseas as well as sets a set of requirements to protect developing countries and seeks to prevent targeted recruitment from developing nations who are experiencing shortages of healthcare staff[13]. Although the UK code of practice is directed at recruitment from non-EU (developing) countries, basic principles such as refraining from targeting developing countries - unless there is an explicit government-to-government agreement to support recruitment activities in order to prevent a drain on valuable human resources[14] - could be used as an inspiration for drafting a code of conduct which could be used for all Member States.

Similarly, the European Federation of Nurses Associations has developed good practise guidelines on recruiting healthcare professionals. These guidelines suggest that before hiring healthcare professionals, the employers should contact the professional nursing association in the source country to obtain their views on whether recruitment can be supported without undermining local healthcare system[15], and could also be used as inspiration for a common EU code of practice applicable to the recruitment of health care professionals between Member States, as well from third countries.

Policy Option: Establishment of an EU Compensation Fund

A way of compensating Member States hit particularly hard by the migration of health professionals could be to establish an EU fund to compensate the Member States for the educational costs for health professionals going abroad. The funding could be financed directly by Member States according to their "imports" of health professionals, meaning that the more health professionals a Member State decides to employ, the more funding will have to be paid. The compensated Member States should then be required to earmark the funding they receive for education of health professionals.

3.3.2 Ensuring equal level of training across Europe

Although perhaps reaching somewhat beyond what could or should be contained within the current directive proposal, the question of how to ensure a homogeneous standard of training across Europe might be considered. A new legal framework on mutual recognition of health professionals' qualifications has been drawn up (Directive 2005/36/EC of the European Parliament and of the Council on the recognition of professional qualifications). The aim of the directive is to establish rules according to which a Member State shall recognise professional qualifications obtained in one or more other Member States.

[12] European Commission, DG Health and Consumer Protection (SANCO) (2006): High Level Group on health services and medical care: Report on the work of the High Level Group in 2006
[13] http://www.nhsemployers.org/primary/workforce-551.cfm
[14] UK Department of Health (2004): Code of Practise for the international recruitment of healthcare professionals
[15] European Federation of Nurses Associations (EFN): EFN Good Practice Guidance for International Nurse Recruitment

This implies that the legal framework for recognising professional qualifications across Europe is in place. However, mutual recognition of professional qualifications does not necessarily mean that the training received by the health professionals has the same content or standard. One of the things that could ease the process of mutual recognition of professional qualifications is to develop a common curriculum to be used in all academic institutions educating health professionals, thus making it easier to recognise the qualifications obtained in another Member State. The process of creating the curricula should be initiated by international associations of health professionals as well as the universities educating the health professionals. The EU could contribute with funding for developing and distributing the curriculum.

Continuous career development in the form of training periods after graduation to achieve a certain specialisation is also one of the issues that could be included in the mutual recognition of professional qualifications. This is currently not covered in the directive on recognition of professional qualifications and could therefore advantageously be an initiative commenced by the international associations of health professionals.

3.4 Mutual recognition of prescriptions

Article 14 of the proposal for a directive states that if a medicinal product is authorised for marketing in a particular Member State according to the Directive on medicinal products

(Directive 2001/83/EC), this Member State must acknowledge a prescription issued in another Member State for this product, unless significant public health considerations are at stake, or there are legitimate and justified doubts about the authenticity or content of the prescription.

According to recital 39 this does not mean that the Member State of affiliation must reimburse the costs of the medicinal product if it is not within the benefits covered by the social security system of affiliation.

This article seems rather clear but could possibly be further clarified through more precise indications of when it may be justified to deny recognition of the prescription with reference to significant public health considerations. More precise rules for the formatting of prescriptions could also be prepared in order to ensure that doubts do not arise concerning the authenticity of prescriptions – e.g. rules on format, contents, signature, doctor's authorisation number etc.

The article does not include situations where the prescription covers a medicinal product which is not marketed in the patient's country of affiliation but which is used in the Member State of treatment. Recital 27 states that the patient has the right to be treated with such a product, even if it is not authorised for marketing in the Member State of affiliation. This does not however mean that the patient is entitled to bring the prescription back to his Member State of affiliation and demand the medicine in question. The solution could be that all Member States accept the use of medicinal products which have been approved for marketing in another Member State. This would not necessarily require that the patient should be able to acquire the product at his local pharmacy, but that the patient would, for instance, be allowed to buy the product over the Internet and have it delivered.

As regards reimbursement of prescribed medicine the basic principle of the proposed directive is that no new rights can be afforded through this directive. Thus, if a certain medicinal product is not reimbursed in the Member State of affiliation, the patient cannot demand reimbursement with reference to this proposed directive.

Policy options:

1. *Member States are required to reimburse any medicine legally prescribed in another Member States. This is really NOT an option, as it contradicts e.g. Art. 6.1 of the proposed directive.*
2. *Member States are not required to reimburse medicines prescribed in another Member State for which patients are not entitled to reimbursement in their home country. Member States shall maintain a list of the (types of) medicines not reimbursed, to be made available in a standard (EU) format to health professionals and health authorities in connection with the measures mentioned in Art. 14.2, and to patients through easily accessible information sources, incl. electronic means (cf. Art 10).*

3.5 European Reference Networks

The proposal for a Directive on Patient's rights in cross-border healthcare calls on the Member States to develop European reference networks. More specifically, the proposal for a directive states that it "provides for cooperation in the specific areas where the economies of scale of coordinated action between all Member States can bring significant added value to national health systems. This is the case for European reference networks"[16].

In the Member States, there is no uniform definition on reference networks and the process of identifying, selecting and designating centres of reference varies markedly from one country to another[17]. In terms of European Reference Networks, a High Level Group on Health Services and Medical Care established by DG SANCO adopted in 2005 a document on its work on health services and medical care defining the main criteria for European reference centres. In 2006 a related document was adopted on options for a procedure for identification and development of European reference networks[18]. Hence, the overall guidelines for the European reference networks are in place.

3.5.1 Implications from the European Reference Networks on accreditation procedures for national networks

With respect to the **implications from the European Reference Networks on the accreditation procedures for national healthcare professional networks,** the European reference networks do not have any immediate implications on the national healthcare professional networks. It is rather the other way around, meaning that the European Reference Networks uses the accreditation results from the national networks to assess the participants wishing to join the European Network. However, it is likely in the future, when the European Reference Networks have functioned a bit longer, that the European Reference Networks will bundle the knowledge from different Member States and create care of even higher quality than today. This could mean that the knowledge obtained on how reference networks function in other countries could affect the accreditation procedures in the national network. For instance, many European Reference Networks have as a goal to be multi-disciplinary. Over time, it could become an objective for the national networks, if the multi-disciplinary approach proves to be advantageous in ensuring better healthcare. It could also be that the knowledge created in the European Reference Networks sets new and higher standards for the Healthcare stakeholders wishing to join the national networks and thus affect the national accreditation procedures[19].

[16] Commission of European Communities (2008): Proposal for a Directive of the European Parliament and the Council on the Application of Patient's Rights in Cross-border Healthcare (COM(2008) 414 final)
[17] http://ec.europa.eu/health/ph_threats/non_com/rare_8_en.htm
[18] http://ec.europa.eu/health/ph_threats/non_com/rare_8_en.htm
[19] Interview with Stuart Elborn, Professor of Respiratory Medicine, Queens' University Belfast and involved in the European Center of Reference Network for Cystic Fibrosis (ECORN-CF)

Further, as stated below there are no homogeneous processes across Member States for identifying and selecting the reference centres[20]. The European Reference Networks may have an effect on this as they can help in aligning and setting the standards for the process of accrediting national reference networks.

3.5.2 Conditions and criteria for healthcare providers wishing to join European Reference Networks

As mentioned, the High Level Group established by DG SANCO has suggested a number of conditions for European reference centres/networks. These are listed below[21]:

- Sufficient activity and capacity to provide relevant services at a sustained level of quality
- Capacity to provide expert advice, diagnosis or confirmation of diagnosis, to produce and adhere to good practice guidelines and to implement outcome measures and quality control
- Multi-disciplinary approach;
- High level of expertise and experience, as documented through publications, grants or honorific positions, teaching and training activities, etc.
- Strong contribution to research
- Involvement in epidemiological surveillance, such as registries
- Close links and collaboration with other expert national and international centres, and capacity to network
- Close links and collaboration with patient associations, where they exist
- Appropriate arrangements for patient referrals from other EU countries
- Appropriate capacities for diagnosing, following-up and managing patients, with evidence of good outcomes, where applicable

The conditions can serve as a starting point for setting up conditions and criteria for the healthcare providers wishing to join the European reference networks, as it is the combined effort of the members of the networks that should create the conditions that make it possible to function successfully as a European reference network.

In order for the reference networks to uphold the objectives stated in the proposal for a directive of among others realising the potential of European cooperation and helping to share knowledge and provide training for healthcare professionals[22], the healthcare providers wishing to join a European Reference Network will be reviewed by a team of healthcare experts to ensure that they live up to standards with respect to reaching the objectives set for the European reference networks. The criteria that they should live up to in order to reach the objectives are linked to the criteria for being appointed a European reference Network and include the following:

[20] http://ec.europa.eu/health/ph_threats/non_com/rare_8_en.htm
[21] http://ec.europa.eu/health/ph_threats/non_com/rare_8_en.htm
[22] Commission of European Communities (2008): Proposal for a Directive of the European Parliament and the Council on the Application of Patient's Rights in Cross-border Healthcare (COM(2008) 414 final)

- Expertise and experience of the members of the national healthcare networks: In order to contribute with knowledge, provide training for health professionals and provide quality and safety benchmark to help develop and spread best practise, it is recommended that the expertise and experience of the potential members of the reference networks are thoroughly evaluated in order to ensure that the network possess the relevant qualifications to meet the objectives.
- Strong contribution to research: One of the ways of ensuring that the healthcare members can contribute strongly to developing best practise could be to ensure that at least some of the members in the network contribute strongly to research in their home country or cross-border, and thus are on the forefront of their field of expertise.
- Quality in the work being done on national level: A way to ensure high quality in the European reference networks is to review the quality of the potential members' work on national level.
- Complementary expertise in order to ensure a multi-disciplinary approach: in order to help to realise the potential of European cooperation, to share knowledge and to develop and spread best practice, it is important to get different inputs on particular fields. Ensuring that the potential members of the reference networks have complementary expertise can help creating synergies and ensuring high standards in healthcare.
- Ability to network on a national/international level: Both in order to spread best practise, but also to ensure that the best capacities are involved in the reference networks, it is important to review whether the potential members of the reference networks have the ability to network, both on an international and national level.

Moreover, in order to ensure that especially the objectives from the proposal for a directive of realising the potential of European cooperation and knowledge-sharing are met, it is important to require that the members of the network commit themselves to a certain level of involvement. Otherwise it is difficult to realise the full potential of the cooperation, share knowledge and possibly create synergies that can help to provide high-quality and cost-effective care and help realising the potential of the internal market in this area by maximising the speed and scale of diffusion of innovations in medical science and health technologies as stated in the proposal for a directive.

Several pilot projects on European reference networks have been funded under DG SANCO's Public Health Action Programme. In order to obtain further information on the conditions and criteria for potential members of the European reference networks, these projects should be evaluated and best practise examples on how to involve national healthcare providers and professional networks be gathered.

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