EUROPEAN
COMMISSION

Brussels, 10.3.2014
C(2014) 1408 final

COMMISSION DELEGATED DECISION

of 10.3.2014

setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Grounds for and objectives of the Decision

Article 12(4)(a) of the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare[1] requires the Commission to support the development of European Reference Networks by adopting a list of criteria and conditions that the European Reference Networks must fulfil and the conditions and criteria required from healthcare providers wishing to become a Member of a European Reference Network.

The Members of a European Reference Network will cooperate amongst themselves in a dedicated field of expertise.

The Directive establishes that any healthcare provider located in a Member State may apply to become a Member of a European Reference Network, in accordance with the legislation of the Member State where it is established, and the application will be successful if all pre-set criteria and conditions are met.

General context

All health systems in the European Union seek to provide high quality and cost effective healthcare. This is particularly difficult to achieve for patients who have conditions requiring a concentration of resources or expertise, even more so for those suffering from rare diseases, as expertise is scarce.

While co-operation in healthcare between Member States has increased following the development of EU health policy, co-operation mainly consists of bilateral agreements (for example in geographically neighbouring areas) or common projects in specific fields of knowledge like by instance clinical trials, training or research activities. To complement these arrangements, in the last decade the EU has supported some networks through the EU Health and Research Programmes in particular in the area of rare diseases. More recently, in 2013, the Commission launched a call for two additional pilot networks on paediatric cancer and neurological complex diseases under the Health Programme.

Establishing European Reference Networks bringing together highly specialised healthcare providers in different Member States represents a clear added value for the EU and will help to provide affordable, high-quality and cost-effective healthcare to patients with conditions requiring a particular concentration of resources or expertise. This will also improve patients' access to the best possible expertise and care available in the EU for their condition. Expected benefits are improvements in services delivery, working systems, patient pathways, clinical tools and earlier adoption of scientific evidence.

Networks could also be focal points for medical training and research, information dissemination and evaluation.

This is why Directive 2011/24/EU 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, as the objectives of the Networks set in article 12 of the Directive – e.g. European co-operation on highly specialised healthcare, pooling of knowledge, improvement of diagnosis and care in medical domains where expertise is rare, helping Member States with insufficient number of

[1] OJ L 88, 04.04.2011

patients to provide highly specialised care - cannot be sufficiently achieved by the Member States by themselves and can be better achieved at Union level.

Networks will also help to maximise the speed and scale of diffusion of innovations in medical science and health technologies, and would thus bring benefits to patients and healthcare systems as well as helping to promote the highest possible quality of care.

Accessibility to high quality and safe healthcare for patients suffering from certain diseases varies across the EU and in particular in conditions that require a high concentration of resources and expertise. There are studies in some specific areas like in the case of cancer care, showing a relation between the frequency and experience of performing a particular treatment or procedure and the quality of the results. More efficient and coordinated sharing of resources and expertise would therefore benefit patients and healthcare systems by reducing differences in the quality and outcomes of the healthcare.

Highly specialised healthcare generally requires significant investments in human and technical resources and structures that need to be developped through dynamic and continuous updating of knowledge and technologies. This may require organisational and planning decisions within the health system, leading to concentration of resources and cases.

Most Member States have thus already invested in centres with well recognised expertise able to perform a particularly complex procedure or treatment but then still lack expertise in other fields of medecine, where centres in other Member States might excell. These disparities and heterogenity have important consequences in a number of low prevalence diseases and translate into inequalities in access to healthcare within the EU.

Each Member State is competent for the financing, organisation and management of its healthcare system and dependant on its own resources, infrastructure and know-how. There is no permanent platform at EU level to construct partnerships on healthcare and to take advantage of their potential synergies and economies of scale. Such partnerships would enhance the mobility of expertise and produce benefits for patients, professionals, managers and healthcare authorities.

Expected benefits are improvement in services delivery, working systems, implementation of patient pathways, clinical tools and earlier adoption of the scientific evidence.

Actions foreseen in the Commission Delegated Decision have no additional budgetary impact on the EU budget, as actions will be financed through appropriations already foreseen in the official financial programming of the Commission.

Existing provisions in the area of the Decision

In addition to Directive 2011/24/EU, the following measures are relevant for European Reference Networks:

- Charter of Fundamental Rights of the European Union[2]
- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
- Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

[2] OJ C 83, 30.3.2010

- Council Conclusions of 22 June 2006 on Common values and principles in European Union Health Systems
- Council Recommendation of 8 June 2009 on an action in the field of rare diseases[3]
- Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections[4]

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Consultations were carried out from the very beginning of the process, in order to prepare this Decision, in compliance of Article 12(4)(a) of Directive 2011/24/EU. The methods used were:

- The sending of a questionnaire to Member States on the Directive, including a section on European Reference Networks, in order to get an overview of the main opinions on the establishment of European Reference Networks and possible obstacles.
- The creation of the Cross-border healthcare expert group, consisting of experts from Member States, which provided advice to the Commission. At several meetings in 2012 and 2013 the expert group addressed the list of specific criteria and conditions that healthcare providers wishing to join European Reference Networks will have to fulfil.
- Three workshops with independent experts on different elements and domains related to the criteria of the European Reference Networks and their Members were also organised. Moreover, a wide range of stakeholders, including European healthcare providers, medical professionals, patient organisations and consumer organisations were consulted.
- A public consultation to get input on the criteria to be used in the process of identification and designation of healthcare providers as Members of a Network. The Commission received 138 responses to this consultation from a wide range of stakeholders, including, inter alia, health professionals' organisations, healthcare providers, insurers and patients. A majority of the responses were clearly supportive of the concept and of the proposed criteria. The contributions included some specific proposals of supplementary criteria and examples of relevant diseases or group of diseases to be addressed by the Networks. These replies were taken into account during the preparatory work on this Decision.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

Legal basis

Article 12(1) of Directive 2011/24/EU establishes that the Commission shall support Member States in the development of European Reference Networks.

Articles 12(4)(a) of this Directive requires the Commission to adopt a list of specific list of criteria and conditions that the European Reference Networks must fulfil and the conditions and criteria required from healthcare providers wishing to join these Networks must fulfil.

Recital 54 of this Directive notes that the main added value of European Reference Networks is to facilitate improvements in access to diagnosis and delivery of high-quality, accessible

[3] OJ C 151, 3.7.2009
[4] OJ C 151, 3.7.2009

and cost-effective healthcare in the case of patients who have a medical condition requiring a particular concentration of expertise or resources, particularly in medical domains where expertise is rare. It further clarifies that European Reference Networks could also be focal points for medical training and research, information dissemination and evaluation, especially for rare diseases. Additionally, recital 60 foresees a main role for the Commission in the establishment of criteria and conditions that shall be fulfilled by European Reference Networks.

Subsidiarity principle and proportionality principle

This Decision supplements Directive 2011/24/EU by establishing the criteria and conditions to become part of European Reference Networks.

The **principle of subsidiarity** requires that the Union shall act only if and insofar the objectives of the proposed action cannot be sufficiently achieved by the Member States (necessity test), but can rather, either by reason of the scale or effects of the proposed action, be better achieved at Union level (test of EU value added).

The measures introduced by some Member States in selecting their Centres of Expertise vary broadly in terms of scope and effectiveness. It is important therefore to establish EU common criteria rather than rely on national ones, to avoid inequalities in the criteria and procedures to designate a healthcare provider as Member of a European Reference Network.

It can therefore be concluded that the objectives of Directive 2011/24/EU can be better achieved through the establishment of EU criteria rather than through national criteria and conditions of varying scope, ambition and effectiveness.

Under the **principle of proportionality**, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties.

This Decision is fully in line with the principle of proportionality since it does not aim to harmonise any law.

This measure is limited to setting up the criteria and conditions that European Reference Networks and their Members should fulfil and has no impact on existing national systems. Member States are not required to create any new infrastructure. On the contrary, existing centres are encouraged to apply to become part of European Reference Networks and their participation will remain voluntary and will be proposed, in accordance with the legislation of the Member State where they are established.

COMMISSION DELEGATED DECISION

of 10.3.2014

setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare[5], and in particular point (a) of Article 12(4) thereof,

Whereas:

(1) Article 12 of Directive 2011/24/EU provides that the Commission is to support the Member States in the development of European Reference Networks ('Networks') between healthcare providers and centres of expertise in the Member States, in particular in the area of rare diseases[6]. For the purposes of this, the Commission shall adopt a list of specific criteria and conditions that must be fulfilled by European Reference Networks and healthcare providers wishing to join and become a Member of a Network ('Member'). The Networks should improve access to diagnosis, treatment and the provision of high-quality healthcare to patients who have conditions requiring a particular concentration of resources or expertise, and could also be focal points for medical training and research, information dissemination and evaluation, especially for rare diseases.

(2) According to Article 12(2) of Directive 2011/24/EU, each Network is to select at least three objectives from the list laid down in therein 12(2) of Directive 2011/24/EU and demonstrate that it has the necessary competences to pursue them effectively. In addition, Networks are required to fulfil the list of tasks or characteristics laid down in Article 12(4)(a)(i)-(vi) of Directive 2011/24/EU. This Decision sets out the specific list of criteria or conditions that will ensure the Networks fulfil these tasks. These criteria and conditions should provide the basis for the establishment and evaluation of the Networks.

(3) Among the set of criteria and conditions necessary to enable Networks pursue the applicable objectives of Article 12(2) of Directive 2011/24/EU the Decision provides a list of criteria on the governance and coordination of the Networks that should ensure their transparent and effective functioning. Although Networks should be allowed to have different organisation models, it is appropriate to require that they all choose one of their Members as the coordinating Member. The coordinating Member shall appoint one person acting as the coordinator of the Network ('Coordinator'). They should be governed by a board of the Network ('Board') composed of representatives from each

[5] OJ L 88, 4.4.2011, p. 45.
[6] COM(2008) 679 final

Member in the Network. The Board should be in charge of producing and adopting the rules of procedure, work plans and progress reports and any other documents related to the activities of the Network. The Coordinator, assisted by the Board, should support and facilitate the internal coordination within the Network and with other healthcare providers.

(4) The provision of highly specialised healthcare, one of the criteria to be fulfilled by the Networks, should be based on high quality, accessible and cost-effective healthcare services. It requires experienced, highly skilled and multidisciplinary healthcare teams and, most likely, advanced specialised medical equipment or infrastructures which commonly imply concentration of resources.

(5) Healthcare providers who apply for membership of a Network should demonstrate that they fulfil the criteria and conditions laid down in this Decision. These criteria and conditions should guarantee that the services and healthcare are provided according to the highest possible quality criteria and available clinical evidence

(6) The required criteria and conditions for a healthcare provider would vary depending on the diseases or conditions specifically addressed by the Network of which they want to become a Member. It therefore appears necessary to establish two sets of criteria and conditions: a first set of horizontal criteria and conditions that should be fulfilled by all healthcare providers wishing to join a Network, regardless of the field of expertise or the medical procedure or treatment they perform, and a second set of criteria and conditions that may vary depending on the scope of the concrete area of expertise, disease or condition addressed by the Network they wish to join.

(7) Among the first set of horizontal and structural criteria and conditions, those related to patients empowerment and patient-centred care; organisation, management and business continuity; research and training capacity appear to be essential in order to ensure that the objectives of the Networks are met.

(8) Further horizontal and structural criteria and conditions related to the exchange of expertise, information systems and eHealth tools should help developing, sharing and spreading information and knowledge and fostering improvements in the diagnosis and treatment of diseases within and outside the Networks and to collaborate closely with other centres of expertise and networks at national and international level. Interoperable and semantically compatible information and communication technology (ICT) systems would facilitate the exchange of health data and patients' information, and the establishment and maintenance of shared databases and registries.

(9) The ability to have an efficient and secure exchange of health data and other patient information as well personal data of the healthcare professionals in charge of the patient is a crucial aspect for the successful functioning of the Networks. The exchange of data should in particular take place in accordance with the specified purposes, necessity and legal grounds for the processing of data and be accompanied by appropriate safeguards and rights of the data subject. Personal data should be processed in compliance with Directive 95/46/EC[7].

(10) This Decision respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union, as referred

[7] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 81, 23.11.1995, p. 31).

to in Article 6 of the Treaty on European Union and notably the right of human dignity, the right to the integrity of the person, the right to the protection of personal data and the right of access to health care. This Decision must be applied by the Member States in accordance with the rights and principles guaranteed in the Charter.

(11) In particular, the Charter requires that in the field of biology and medicine the free and informed consent of the person concerned must be respected. As Clinical Trials could likely be one of the areas of work of the Networks it is important to recall that an extensive set of rules for the protection of subjects in clinical trials is foreseen in Directive 2001/20/EC.[8]

(12) In order to ensure the exchange of personal data in the context of the Networks, procedures concerning informed consent for processing this data could be simplified by using one single common consent model that needs to be subject to the requirements set out in Directive 95/46/EC with regard to the consent of the data subject.

(13) The criteria and conditions related to expertise, clinical practice, quality, patient safety and evaluation should help in developing and spreading the best practices for quality and safety benchmarks. They should also thus ensure the offer of a high level of expertise, produce good practice guidelines, implement outcome measures and quality control and follow a multi-disciplinary approach as required by Article 12(4) of Directive 2011/24/EU.

(14) Member States with no Member of a given Network may decide to designate healthcare providers with a special link to a given Network, following a transparent and explicit procedure. Those providers might be designated as Associated National Centres focusing in the provision of healthcare or as Collaborative National Centres focusing in the production of knowledge and tools to improve the quality of care. Member States may also wish to designate a national coordination hub with all types of Networks. That might help Member States to pursue Article 12(3)(a) of Directive 2011/24/EU particularly if the objectives of the Network are among those listed under Article 12(2)(f) and (h) of Directive 2011/24/EU. The Coordinator should facilitate the cooperation with these healthcare providers linked to a Network. Those healthcare providers shall support the objectives and respect the rules of the Network and share the work related with the cooperation activities of the Network.

HAS ADOPTED THIS DECISION:

CHAPTER I
GENERAL PROVISIONS

Article 1
Subject matter

This Decision lays down

---

[8] Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

(a) the criteria and conditions that the Networks referred to in Article 12 of Directive 2011/24/EU must fulfil, and

(b) the criteria and conditions required from healthcare providers wishing to join a Network referred to in Article 12 of Directive 2011/24/EU.

Article 2
Definitions

For the purpose of this Decision and in addition to the definitions laid down in Article 3 of Directive 2011/24/EU the following definitions shall apply:

(a) 'Member of a Network' means healthcare providers that are in compliance with the list of criteria and conditions laid down in Article 5 of this Decision and have been awarded with the membership of a given Network;

(b) 'Highly specialised healthcare' means healthcare that involves high complexity of a particular disease or condition in its diagnosis or treatment or management and high cost of the treatment and resources involved;

(c) Complex disease or condition' means a particular disease or disorder which combines a number of factors, symptoms, or signs that requires a multidisciplinary approach and well-planned organisation of services over time because it implies one or several of the following circumstances:

- a large number of possible diagnoses or management options and comorbidity
- difficult interpretation of clinical and diagnostic tests data
- a high risk of complications, morbidity, or mortality related to either the problem, the diagnostic procedure or the management.

(d) 'Multidisciplinary healthcare team' means a group of health professionals from several fields of healthcare, combining skills and resources, each providing specific services and collaborating on the same case and coordinating the healthcare to be provided to the patient;

(e) ‘Informed consent under the framework of European Reference Networks' means any freely-given, specific, informed and explicit indication of a subject's wishes by which he or she, either by a statement or by a clear affirmative action, signifies agreement to the exchange of her or his personal and health data between healthcare providers and Members of a European Reference Network as provided in this Delegated Decision.

CHAPTER II
EUROPEAN REFERENCE NETWORKS

Article 3
Criteria and conditions for Networks

Networks shall fulfil the criteria and conditions necessary to enable them pursue the applicable objectives of Article 12(2) of Directive 2011/24/EU set out in Annex I.

Article 4
Membership of the Networks

Networks shall be composed of healthcare providers identified as Members of the Network. For each network, one Member will act as Coordinator.

CHAPTER III
HEALTHCARE PROVIDERS

Article 5
Criteria and conditions for applicants of membership of a Network

All applicants wishing to join a given Network must have knowledge and expertise or offer a diagnosis or a treatment that focusses on a disease or condition falling within the field of specialisation of the Network and shall fulfil the criteria and conditions set out in Annex II.

CHAPTER IV
FINAL PROVISION

Article 6

This Decision shall enter into force on the 10th day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 10.3.2014

For the Commission
The President
José Manuel BARROSO