

COMMISSION DELEGATED DECISION**of 10 March 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)**

(2014/286/EU)

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 ⁽¹⁾, 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 ⁽²⁾. 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 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 multi-disciplinary healthcare teams and, most likely, advanced specialised medical equipment or infrastructures which commonly imply concentration of resources.

⁽¹⁾ OJ L 88, 4.4.2011, p. 45.⁽²⁾ COM(2008) 679 final.

- (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 health-care 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 of the European Parliament and of the Council ⁽¹⁾.
- (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 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 healthcare. 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 of the European Parliament and of the Council ⁽²⁾.
- (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.

⁽¹⁾ 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 281, 23.11.1995, p. 31).

⁽²⁾ 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).

- (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:

- (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 March 2014.

For the Commission
The President
José Manuel BARROSO

ANNEX I

CRITERIA AND CONDITIONS TO BE FULFILLED BY THE NETWORKS

- (1) In order to enable Networks pursue the applicable objectives of Article 12(2) of Directive 2011/24/EU, each Network shall:
 - (a) provide highly specialised healthcare for rare or low prevalence complex diseases or conditions;
 - (b) have a clear governance and coordination structure including at least the following:
 - (i) the Members' Representatives who will represent them within the Network. Each Member shall choose its representative from among the health professionals belonging to its staff;
 - (ii) the Board of the Network that will be responsible for its governance. All Members of the Network must be represented on the Board;
 - (iii) the Coordinator of the Network, chosen from among the health professionals belonging to the staff of the coordinating Member, who will chair the meetings of the Board and represent the Network.
- (2) To fulfil the requirement set out in point (i) of Article 12(4)(a) of Directive 2011/24/EU ('have knowledge and expertise to diagnose, follow up and manage patients with evidence of good outcomes'), the Networks must:
 - (a) promote good quality and safe care to patients suffering from certain diseases and conditions by fostering proper diagnosis, treatment, follow-up and management of patients across the Network;
 - (b) empower and involve patients in order to improve the safety and good quality of the care they receive.
- (3) To fulfil the requirement set out in point (ii) of Article 12(4)(a) of Directive 2011/24/EU ('follow a multi-disciplinary approach'), the Networks must:
 - (a) identify areas and best practices for multi-disciplinary work;
 - (b) be made up of multi-disciplinary healthcare teams;
 - (c) offer and promote multi-disciplinary advice for complex cases.
- (4) To fulfil the requirement set out in point (iii) of Article 12(4)(a) of Directive 2011/24/EU ('offer a high level of expertise and have the capacity to produce good practice guidelines and to implement outcome measures and quality control'), the Networks must:
 - (a) exchange, gather and disseminate knowledge, evidence and expertise within and outside the Network, in particular on the different alternatives, therapeutic options and best practices with regard to the provision of services and the treatments available for each particular disease or condition;
 - (b) promote expertise and support healthcare providers in order to bring local, regional and national provision of healthcare closer to patients;
 - (c) develop and implement clinical guidelines and cross-border patient pathways;
 - (d) design and implement outcome and performance indicators;
 - (e) develop and maintain a quality, patient safety and evaluation framework.
- (5) To fulfil the requirement set out in point (iv) of Article 12(4)(a) of Directive 2011/24/EU ('make a contribution to research'), the Networks must:
 - (a) identify and fill research gaps;
 - (b) promote collaborative research within the Network;
 - (c) reinforce research and epidemiological surveillance, through setting up of shared registries.

- (6) To fulfil the requirement set out in point (v) of Article 12(4)(a) of Directive 2011/24/EU ('organise teaching and training activities'), the Networks must:
- (a) identify and fill training gaps;
 - (b) encourage and facilitate the development of training and continuous education programmes and tools for health-care providers involved in the chain of care (within or outside the Network).
- (7) To comply with the requirement set out in point (vi) of Article 12(4)(a) of Directive 2011/24/EU ('collaborate closely with other centres of expertise and networks at national and international level'), the Networks must:
- (a) exchange and disseminate knowledge and best practices, in particular by supporting national centres and networks;
 - (b) set up networking elements, such as communication tools, and methodologies to develop clinical guidelines and protocols; exchange clinical information in accordance with EU data protection provisions and national implementing measures, in particular Directive 95/46/EC, and Article 3 of this Delegated Decision; develop training alternatives and models and operation and coordination practices, etc.;
 - (c) collaborate with Associated National Centres and Collaborative National Centres chosen by Member States with no Member of a given Network, particularly if the objectives of the Network are among those listed under Article 12(2)(f) and (h) of Directive 2011/24/EU.
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ANNEX II

CRITERIA AND CONDITIONS FOR APPLICANTS FOR MEMBERSHIP OF A NETWORK**1. General criteria and conditions for all applicant healthcare providers**

All applicants wishing to join a Network shall comply with the following criteria and conditions:

- (a) as regards patient empowerment and patient-centred care, applicant providers must:
- (i) have put strategies in place to ensure that care is patient-centred, that patients' rights (such as the right to informed consent; the right to information concerning their own health; the right to access to their medical records; the right to privacy; the right to complain and the right to obtain compensation, the right to be empowered and to participate (for example, through customer relations management strategies, patient education strategies and active engagement strategies for patients and families throughout the healthcare institution)) are respected;
 - (ii) provide clear and transparent information about complaint procedures and the remedies and forms of redress available to both domestic and foreign patients;
 - (iii) ensure feedback on patient experience and the active evaluation of patient experience;
 - (iv) apply personal data protection rules and ensure access to medical records and clinical information in compliance with EU data protection provisions and national implementing measures and in particular with Directive 95/46/EC;
 - (v) ensure that the informed consent of the data subject complies with the requirements set out in Article 2(e) of this Delegated Decision, in particular informed consent given freely, unambiguously and explicitly by the subject or his/her legal representative after being informed of the purpose, nature, significance and implications of the use of his/her personal and health data, if personal health data is exchanged under this Delegated Decision, and being informed of his/her rights under the applicable data protection rules. The given consent should be duly documented;
 - (vi) ensure transparency, including providing information about clinical outcomes, treatment options and the quality and safety standards put in place;
- (b) with regard to organisation, management and business continuity, applicant providers must:
- (i) apply transparent and explicit organisation and management rules and procedures, including in particular the procedures for managing cross-border patients in their area of expertise;
 - (ii) ensure that tariffs are transparent;
 - (iii) have a business continuity plan over a given time frame, including ensuring:
 - the provision of essential medical care in the case of unexpected resource failure, or access or referral to alternative resources if necessary,
 - the maintenance of the stability and technical capacity and expertise of the provider, such as a plan for managing human resources and updating technology;
 - (iv) ensure coordination with and easy access of the provider to other resources or specific units or services necessary for managing patients;
 - (v) have good general facilities, such as surgery theatres, an intensive care unit, an isolation unit, an emergency ward and laboratories;
 - (vi) have the capacity to communicate with relevant post-discharge services, including the capacity for cross-border communication;
- (c) with regard to research and training capacity, applicant providers must:
- (i) have the capacity to provide academic, university or specialised level training;
 - (ii) have human, technical and structural capacity, skill mix and resources;

- (iii) have research capacity, and demonstrated research experience or production in the area of expertise of the Network, at national and international level;
 - (iv) carry out teaching and education activities related to the area of expertise aimed at improving the knowledge and technical capacity of the healthcare providers involved in the same chain of care within and outside the provider facility, such as continuing medical education and distance learning;
- (d) with regard to the exchange of expertise, information systems and e-health tools, applicant providers must:
- (i) be able to exchange expertise with other healthcare providers and to support them;
 - (ii) have established procedures and a framework for ensuring the management, safeguarding and exchange of medical data, including established outcomes, process indicators and patient registers for the specific area of expertise in accordance with the EU data protection legislation, in particular with Directive 95/46/EC, and with Article 2(e) of this Delegated Decision;
 - (iii) be able to foster the use of telemedicine and other e-health tools within and outside their facilities, by fulfilling the minimum interoperability requirements and when possible, using agreed standards and recommendations;
 - (iv) use a standardised information and coding system in line with nationally or internationally recognised systems, for example International Classification of Diseases and complementary codes when appropriate;
- (e) with regard to expertise, good practices, quality, patient safety and evaluation, applicant providers must:
- (i) have a quality assurance or management system and plans including governance and evaluation of the system;
 - (ii) have a patient safety programme or plan consisting of specific goals, procedures, standards and process and outcome indicators focusing on key areas, such as information, a system for reporting on and learning from adverse events; training and education activities; hand hygiene; healthcare related infections; medication errors and the safe use of medication; safe procedures and surgery; safe patient identification;
 - (iii) commit itself to using the best knowledge- and evidence-based health technologies and treatments;
 - (iv) develop and use clinical guidelines and pathways in their area of expertise.

2. Specific criteria and conditions for applicant providers with regard to the area of expertise, disease or conditions the Networks they wish to join focus on

- (a) with regard to competence, experience and outcomes of care, applicant providers must:
- (i) document competence, experience and activity (e.g. the volume of activity, referrals and accumulated experience and when possible, the minimum/optimal number of patients/year, in accordance with professional/technical standards or recommendations);
 - (ii) provide evidence of good clinical care and outcomes according to available standards, indicators and knowledge, and evidence that the treatments offered are recognised by international medical science in terms of their safety, value and potential positive clinical outcome;
- (b) with regard to the specific human, structural and equipment resources and the organisation of care, applicant providers must document:
- (i) the characteristics of human resources such as type, number, qualifications and skills;
 - (ii) the characteristics, organisation and functioning of the specific multidisciplinary healthcare team;
 - (iii) specific equipment within the centre or easily accessible (such as radiotherapy laboratories or hemodynamic facilities), including the capacity, when appropriate and based on the area of expertise, to process, manage and exchange information and biomedical images (such as in the case of radiology x-ray machines, microscopy, video-endoscopy and other dynamic explorations) or clinical samples with external providers.
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