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From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
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To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
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Subject:	ANNEX to the Commission Delegated Decision setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil

Delegations will find attached document Annex to C(2014) 1408 final.

Encl.: Annex to C(2014) 1408 final

EUROPEAN
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Brussels, 10.3.2014
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ANNEXES 1 to 2

ANNEX

to the

Commission Delegated Decision

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

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 healthcare 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.

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.