

## **Criteria of European Reference Networks (ERN)**

### **Article 12 of 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**

#### **CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION**

**Deadline for replies to this Public Consultation: 22.02.2013**

*This document does not represent an official position of the European Commission. It is a tool to explore the views of interested parties on the matter. The suggestions contained in this document do not prejudice the form and content of any future proposal*

*This document is to be read together with 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.*

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## Contents

1. INTRODUCTION AND LEGAL BASE.....	3
2. BACKGROUND.....	4
3. PROCESS AND WORK PLAN .....	5
3.1. Categories of Criteria .....	5
<b>3.1.1. ERN criteria on the targeted diseases or conditions:</b> .....	5
<b>3.1.2. General criteria:</b> .....	6
<b>3.1.3. Specific criteria</b> .....	6
4. ANNEX:.....	6

## 1. INTRODUCTION AND LEGAL BASE

Article 12 of 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<sup>1</sup> (hereafter "the Directive") should support Member States in the development of European Reference Networks.

Recital 54 of the Directive further clarifies that the main added value of the European Reference Networks and therefore of the Centres of Excellence is to facilitate improvements in access to diagnosis and delivery of high-quality, accessible 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.

**Article 12(4)(a) of the Directive** requires the Commission to adopt, via delegated acts, a list of criteria that the networks must fulfil, and the conditions and criteria which providers wishing to join networks must fulfil.

**Table 1. European Reference Network's objectives (Art. 12(4)(a))**

- have knowledge and expertise to diagnose, follow-up and manage patients with evidence of good outcomes, as far as applicable;
- follow a multi-disciplinary approach;
- offer a high level of expertise and have the capacity to produce good practice guidelines and to implement outcome measures and quality control;
- make a contribution to research;
- organise teaching and training activities;
- collaborate closely with other centres of expertise and networks at national and international level;

The Commission is also required to develop and publish criteria for establishing and evaluating European reference networks. And it must facilitate the exchange of information and expertise on the establishment of the networks and of their evaluation. These two points are to be done via implementing acts.

It is important to point out that the first step of this process is to identify already established centres of expertise and to encourage voluntary participation of healthcare providers in the future European Reference Networks.

**Table 2. Delegated and Implementing Acts**

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<sup>1</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF>

**Delegated Acts:** on the list of specific criteria and conditions that ERN and the healthcare providers wishing to join the network must fulfil (Art. 12(4)(a)).

**Implementing Acts:** on the criteria for establishing and evaluating ERN (Art. 12 (4)(b)); and measures to facilitate the exchange of information and expertise for ERN (Art. 12 (4)(c));

To prepare these acts, the Commission will carry out appropriate public and targeted consultations. In respect of delegated acts, the Commission will create the *Cross-Border Healthcare Expert Group* (hereafter the "Expert Group") to act as a forum for this consultation. This expert group will consist primarily of national experts of all Member States.

In the case of the implementing acts, the Commission will be assisted by the Expert Group and will present its proposals to be voted by the Committee on Cross-border Healthcare (hereafter the "Committee") composed of Member States representatives.

## 2. BACKGROUND

The concepts of *centres of reference and European reference network* has been considered as one of the relevant topics in the political, legal and strategic debate on "patient mobility" by all European Institutions and Member States and several important political, legal and technical documents and reports have been produced in the past decade. Key milestones on this topic are listed in the in annex (although this list is not exhaustive).

In this context, the scope for promoting European Reference Networks has always been wider than rare diseases. The Directive maintains this approach by including within scope those conditions that would benefit from the future of reference networking.

According to the preliminary results of the answers of Member States to the questionnaire sent by the Commission, most Member States are either in the process of developing such systems, or are yet to start the process at all. There are good examples of national and regional systems already in some Member States.

A preliminary analysis of the existing systems shows that, despite the different names or procedures, there are important elements shared by those Member States, in particular as regards:

- The processes or criteria related with diseases or conditions in order to be considered under the scope of the ERN;
- The criteria to fulfil by the centres wishing to join a European Reference Network;
- The processes and guidelines to refer and follow up patients;
- The bodies and procedures for the management, monitoring and evaluation of the designated centres.

These systems are, in general, in line with the goals and philosophy of the Directive and therefore the methodologies, experiences and lesson learned in these countries should be the starting point for the future system of ERN.

### **3. PROCESS AND WORK PLAN**

It seems appropriate to take a step-by-step approach to this work, and to ensure that it is rigorous and evidence-based. This is essential for the success of the project.

SANCO services are now performing a mapping exercise and a description of the different models and procedures currently in place at European level, based on an exhaustive review of the state of the art and on the contributions provided by Member States. Sharing and discussing different possible scenarios will facilitate a common understanding of the scope and contents to be included in the legal acts.

The delegated and implementing acts will define the criteria and conditions the Networks and healthcare providers should address. including those for the selection and designation of the healthcare providers to be considered members of the ERN, and establish the methodology for the development of the whole process. The legal acts will also include the criteria and rules for the adequate management, monitoring and evaluation of the networks.

#### **3.1. Categories of Criteria**

The European Commission has identified three sub-categories of criteria:

##### ***3.1.1. Criteria related with the scope of ERN and the targeted diseases or conditions:***

Characteristics which a condition, disease or techniques should fulfil to be considered for inclusion in the scope of the future ERN.

- Highly specialised healthcare
  - Complexity of diagnosis and treatment
  - High cost of treatment and resources
  - Need of advanced/highly specialized medical equipment or infrastructures
  
- Need of a particular concentration of expertise and resources
  - Rare expertise/need of concentration of cases
  - Low prevalence/incidence/number of cases
  - Evaluated experiences of Member States
  
- Based on high-quality, accessible and cost-effective healthcare
  - Evidence of the safety, favourable risk-benefit analysis and potential positive outcome (clinical)
  - Feasibility and evidence of value of the treatment
  - Economic analysis and in particular cost-effectiveness

It should be taken in account the current scientific knowledge, the needs of the citizens and the priorities of Member States.

### **3.1.2. General criteria of the centres wishing to join a European Reference Network :**

General and common fields and elements required for any type of health care provider to be designated as centre of reference (general criteria), such as:

- Overall organisation and management
- Patients empowerment and centred care
- Framework of patient care, clinical tools and health technology assessment
- Framework and policies on quality, patient safety and evaluation
- Business continuity, contingency planning and response capacity
- Information system, data protection, technology and e-health tools and applications
- Overall framework and capacity for research and training
- Specific Commitment of the Management/Direction of the Centre/Hospital to ensure a full and active participation in the ERN

### **3.1.3. Specific criteria regarding the areas of expertise**

For being selected as a centre of reference for a concrete disease or condition (hereafter disease specific criteria). Further to the general criteria, the quantitative or qualitative requisites would be defined for each of the selected diseases or conditions in the following domains:

- Competence, experience and good outcomes and care
- Specific resources & organisation Human resources
  - Team / centre organisation
  - Structural conditions
  - Specific equipment
  - Other required complementary and coordinated units or services to the specific centre
- Patient care pathways, protocols and clinical guidelines in the field of expertise
- Research, training, health technology assessment in the field of expertise
- External coordination, care management and follow-up of patients
- Information system and surveillance

## **4. ANNEX:**

**Background on Centres of Reference and ERN: Key milestones in the reflection,**

## **political, legal and technical process**

- Council Conclusions and Ministerial Conference on Patient Mobility (2002)
- High Level Process of reflection on patient mobility and healthcare developments in the European Union (2003).
- Commission Communication on the follow up of the High Level Process (2004)
- Creation of the High Level Group (HLG) on Health Services and Medical Care (2004)
- Creation and works produced by the working party on centres of reference of the HLG (2005-2010)
- Report of the HLG recommending a set of agreed general principles on European centres of reference (2005-2006)
- Commission's proposal on Community action on health services' (2007)
- Research FP5, FP6 & FP7 including ERN and Centres of Reference in Rare Diseases as a priority.
- EU first and second Public Health Programme (2003-2013)
- Reports & recommendations on ERN and Centres of excellence in Rare Diseases of the Taskforce for Rare Diseases (2004-2010) and the EUCERD (2010-2012).
- Adoption of the Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare (Art. 12)