Criteria for Networks and Providers Implementation Framework

Directive of patients' rights in cross-border healthcare

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Overview

✓ Context, scope and objectives

✓ Legal measures:

  Criteria for networks and providers
  Assessment and establishment

✓ Timeline for the implementation
Key issues addressed by the Directive

**Directive 2011/24/EU of patients' rights in cross-border healthcare**

- Right to **choose and be reimbursed** for healthcare **provided** by public or private providers located in the EU

- More **transparency about their rights**, treatment options or, the quality and safety levels of healthcare providers

- Strong focus on **cooperation among Member States**

**Entry into force at National level 25 October 2013**
Scope and Context

Cooperation between MS: Article 12 European Reference Networks

Networks of healthcare providers aiming at

**Improving quality and safety and access to highly specialised healthcare**

- Patients affected by **rare or low prevalence and complex diseases**
- Added **value** at EU level
- Need of **cooperation**:
  - Scarcity knowledge / need education
  - Complexity / high cost
- **Multidisciplinary approach** (different specialities/areas of knowledge)
Cross-border Healthcare Expert Group

SANCO

Delegated Decision

Exchange of information and expertise for ERN

Implementing Decision

criteria and conditions for providers & Networks

enter into force 27 May 2014

Looking at best practices: MS and Centres visits

Public Consultation

Advise from
- EUCERD
- EPAAC
- PARENT

Technical Brainstorming & workshops

Scientific societies
Patients associations

Reports and technical papers

2011 - 2014

2011 - 2014

2011 - 2014
Legal acts on ERN

**HOW**

**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)

**WHAT**

**COMMISSION IMPLEMENTING DECISION**

of 10.3.2014

setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks

(Text with EEA relevance)

Entry into force 27 May 2014
Content of the delegated decision

6 sets of Criteria for Networks

5 sets of general criteria for members

2 sets of specific criteria for members
European Reference Networks: networking dimension

- **Key issues:**
  - Exchange of expertise and clinical data through the network and across the EU
  - Swift and smooth contact between providers and between patients and providers at a distance
  - Collaborative/cooperative actions and systems

- **Networking activities and availability of specific network tools -It solutions- are the basis for this project.**
Remote guidance and Diagnosis

Secure exchange of Patient information, databases/registries

Remote monitoring and follow-up

Virtual clinical/tumour boards

Remote training

Networking elements, communication and eHealth solutions

Local Healthcare Provider

Member

Member

Tele-medicine Tele-consultation

Members
Governance / coordination Networks

- **Transparent and effective** coordination & governance (adequate structures and elements)
- **Networks can be flexible** & have different architectures and internal relations **but** there are key organizational features.

Diagram:
- European Reference Network
  - Network Coordinator
  - Board of the Network
  - Member A1 (country Y)
    - Centre Representative
    - Member A2 (country Z)
      - Centre Representative
  - Associated National Centre Country Y
  - Collaborative National Centre Country Y
Members of the Networks

**Key issues**

- **Principal constituents** of the European Reference networks
- **Work based in cooperation amongst themselves** in a dedicated field of expertise
- **In accordance with legislation** of their Member States
- **Fulfilment of the criteria** provided in the delegated decision
- **Full responsibilities, tasks and participation in all the technical and governance bodies of the ERN**
- **Acting as a hub (interconnector) between the nat. healthcare providers and the ERN**
All Members in an ERN must have in common:

(a) the expertise they specialise in

(b) certain treatment(s) offered or

(c) disease(s) or health condition(s) they focus on.
1. **Set of horizontal criteria and conditions** to be fulfilled by all healthcare providers regardless of the field of expertise

- **a)** patients empowerment and centred care
- **b)** organisational, management and business continuity
- **c)** research and training capacity
- **d)** exchange of expertise, information systems and e-health tools
- **e)** expertise, good practice, quality, patients safety and evaluation
Member’s specific criteria

Set of specific criteria and conditions may vary depending on the scope of the concrete area of expertise

- document competence, experience and activity
- provide evidence of good clinical care and outcomes
- characteristics of human resources
- organisation and functioning: multidisciplinary healthcare team
- specific equipment within the centre or easily accessible
- communication / interaction at a distance capacity

Based on the evidence and consensus of the scientific, technical and professional community

Bottom up proposals
Main principles agreed with Member States

1. Clear and solid eligibility criteria of the Networks
2. Key role of Member States: endorsement and approval
3. Participation: voluntary and commitment with the rules
4. Transparency and efficiency of the process
5. Based on a strong independent technical assessment
Assessment & evaluation body

institutional or entities with a solid background

- External and independent
- Experience & knowledge on healthcare systems
- Capacity and knowledge to develop methodology (manual and procedures) based on the criteria established in the legal acts
- Capacity to conduct and carry out assessment (pre) and evaluation (post) of the Networks and healthcare providers

Competitive Call
ERN Scenario

Players

1. HCP & Network projects
2. SANCO
3. Member States
4. Technical Independent Body

Call for Networks → Network proposals → Eligibility check → Technical Assessment (criteria & conditions)

Positive Assessment → Approval of Network → Establishment and Membership → Logo award

Networks Functioning

Confirmation (ERN and Members)

Evaluation (criteria, performance and cooperation)
ERN IMPLEMENTATION: the way forward

- **Communication and awareness activities**

- **Preparation of the Assessment Manual and toolkit**

Call for tender n° X concerning the development of a manual and toolbox for the assessment of European Reference Networks: July 2014

- **Framework contract for independent assessment bodies: November 2014**
ERN IMPLEMENTATION: the way forward

Cross-sectorial cooperation and funding sources

✓ Public health program 2014-2020: studies & project grants to approved ERN
✓ RTD horizon 2020 : 2016 research on networks organizational models
✓ Connecting European Facilities (CEF): the eHealth dimension
✓ Structural funds (cross border cooperation)
✓ Social funds (training and better skills)
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<td>Establishment of Networks</td>
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Be prepared

- **2014-2015: Preparation of Network Proposals**
  - Identify clusters of diseases (scope of ERN)
  - Identify qualified healthcare providers and informal networks
  - Establish synergies

- **2015: Guidelines and technical documents** for the Network proposals

- **2015: Call for Networks**
  - Complete Network and individuals proposals and documentation
  - Self-assessment
Don’t forget that this will be a long journey
Thank you!

Further information: