

## Entidade Reguladora da Saúde - ERS (Portuguese Health Regulatory Authority), Portugal

1. Respondent Profile	
1.1 Please indicate the type of organisation on behalf of which you are responding to this consultation:	Healthcare public administration at national level
Please indicate for what the administration is responsible:	Quality, patient safety or clinical governance
1.1.1. Other (please specify):	The Portuguese Health Regulatory Authority is the independent public body responsible for the regulation and supervision of the activity of health care providers in Portugal.
1.2 Please indicate the name of your organisation or centre:	Entidade Reguladora da Saúde - ERS (Portuguese Health Regulatory Authority), <a href="http://www.ers.pt">www.ers.pt</a> .
1.3 Please indicate the country where your organisation/centre is located/has its headquarters or main representative office in Europe:	PT
1.4 Please indicate the number of EU Member States and EEA countries (Norway, Iceland, Lichtenstein) and accessing country (Croatia) in which your organisation conducts business/is represented:	1
1.5 If need be, can we contact you by e-mail to obtain further information on your submission?	Yes
1.5.1 Please provide an e-mail address where we can contact you:	ssilva@ers.pt and mcarmo@ers.pt .
1.6 Please provide us with a contact person (incl jobtitle and daytime phone number):	Ana Sofia Silva and Marta do Carmo, Técnicas Superiores, +351 222392350.
1.7 Please provide additional contact details if needed:	

## 2. Involvement of your organisation in the matter of centres of excellence/reference (COE) and healthcare networks in highly specialised healthcare (HSHC).

2.1 How would you describe your organisation's knowledge of CoE and HSHC?	High
2.1.1 Space for further comments:	ERS regulates the providers that are or have COE and that participate in HSHC. However, ERS is not involved in the definition of health policy nor does it provides health care services.
2.2. What aspects or domains related to the topic of CoE and HSHC would correspond to your organisation's key knowledge? (cross any that applies)	Priorities, description and characteristics of CoE and HSHC Professional performance, clinical practice, quality and safety of specialized healthcare Assessment/evaluation/certification of clinical practice and healthcare providers
2.2.1. Space for further comments:	ERS carries out inspections to facilities and investigates occurrences with adverse impact on quality and safety of healthcare provision, among other aspects. It can propose features of COE and HSHC.
2.3 Is highly specialised healthcare a priority in your organisation's strategies and work plans?	Somewhat
2.3.1 Space for further comments:	
2.4. What specific field of healthcare services/specialities are most relevant for your centre/organisation's field of work?	Other
Please specify:	All health care specialties are equally relevant.

2.5. Has your organisation/centre been directly involved in the design or assessment of professional standards and criteria related with highly specialised healthcare?	Occasionally
2.5.1 Please describe your role in such actions/projects:	ERS has published studies on the organization of public health care supply in hospitals, which addressed specific proposals for COE features, and on patients' referral between public hospitals.
2.6. Has your organisation been involved in projects/activities supported by the Commission in relation with HSHC or professional and technical criteria/standards in highly specialised healthcare?	No
2.7. Do you have concrete examples based on your own organisation's experience or could you provide us with references or links to documents related with professional criteria and standards in highly specialised healthcare/CoE or HSHC (e.g. quality criteria, guidelines, consensus documents)?	Yes
2.7.1 Space for further comments:	ERS's Health Care Evaluation System assesses the overall quality of the health care providers considering clinical excellence, safety, comfort of facilities, patient focus and patient satisfaction.
2.13. What is the scope of the network?	
2.14. Which kind of network?	
2.14.1 Space for further comments:	
2.15. Would you be interested in applying to the process to be considered Centre of Excellence of the future European Reference Network? (1 = not interested at all, 5 = very interested)	
2.15.1 Space for further comments:	

### 3. Proposed criteria for ERN (scope, general and specific criteria)

#### 3.1 Criteria related with diseases or conditions in order to be considered under the scope of the ERN

3.1.1. Need of highly specialised healthcare	5
3.1.1.1. Complexity of the diagnosis and treatment	4
3.1.1.2. High cost of treatment and resources	2
3.1.1.3. Need of advanced/highly specialised medical equipment or infrastructures	5
3.1.2. Need of particular concentration of expertise and resources	5
3.1.2.1. Rare expertise/need of concentration of cases	5
3.1.2.2. Low prevalence/incidence/number of cases	3
3.1.2.3. Evaluated experiences of Member States	4
3.1.3. Based on high-quality, accessible and cost-effective healthcare	5
3.1.3.1. Evidence of the safety and favourable risk-benefit analysis	5
3.1.3.2. Feasibility and evidence of the value and potential positive outcome (clinical)	5
3.1.4. Do you recommend any additional criteria or option that would effectively address the issue?	No

3.1.5. Would you prioritise or suggest any concrete disease or group of diseases to be addressed by the future ERN according to the above criteria?	Yes
3.1.5.1 Explain your proposal in free text:	Treatment of coronary disease, acute stroke, orthopedics and oncological diseases - High prevalence in community. Transplants (liver, kidney, pancreas) - Highly specialized healthcare.

### 3.2. General criteria of the centres wishing to join a European Reference Network

3.2.1. Organisation and management	3
3.2.2. Patients empowerment and centered care	5
3.2.3. Patient care, clinical tools and health technology assessment	5
3.2.4. Quality, patient safety and evaluation framework policies	5
3.2.5. Business continuity, contingency planning and response capacity	4
3.2.6. Information systems, technology and e-health tools and applications	5
3.2.7. Overall framework and capacity for research and training	5
3.2.8. Specific commitment of the management/direction of the centre/hospital to ensure a full and active participation in the ERN	5
3.2.9. Do you recommend any additional option that would effectively address the issue?	Yes

3.2.9.1. Space for further comments:

Geographic location/accessibility, multidisciplinary health care and patient focus, including support to patients' families and accompanying persons.

### 3.3. Specific criteria regarding the areas of expertise

3.3.1. Competence, experience and good outcomes and care 5

3.3.2. Specific resources and organisation: 5

3.3.2.1. Human resources 5

3.3.2.2. Team/centre organisation 5

3.3.2.3. Structural conditions 4

3.3.2.4. Specific equipment 5

3.3.2.5. Presence and coordination with other required complementary units or services 5

3.3.3. Patient care pathways, protocols and clinical guidelines in the field of expertise 5

3.3.4. External coordination, care management and follow-up of patients 4

3.3.5. Research, training, health technology assessment in the field of expertise 5

3.3.6. Specific information systems 4

3.3.7. Do you recommend any additional criteria or option that would effectively address the issue? No

3.3.7.1. Space for further comments: The presented criteria seem to be very thorough.