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

CHAPTER IV

COOPERATION IN HEALTHCARE

Article 12

European reference networks

1 The Commission shall support Member States in the development of European reference networks between healthcare providers and centres of expertise in the Member States, in particular in the area of rare diseases. The networks shall be based on voluntary participation by its members, which shall participate and contribute to the networks' activities in accordance with the legislation of the Member State where the members are established and shall at all times be open to new healthcare providers which might wish to join them, provided that such healthcare providers fulfil all the required conditions and criteria referred to in paragraph 4.

2 European reference networks shall have at least three of the following objectives:

- a to help realise the potential of European cooperation regarding highly specialised healthcare for patients and for healthcare systems by exploiting innovations in medical science and health technologies;
- b to contribute to the pooling of knowledge regarding sickness prevention;
- c to facilitate improvements in diagnosis and the delivery of high-quality, accessible and cost-effective healthcare for all patients with a medical condition requiring a particular concentration of expertise in medical domains where expertise is rare;
- d to maximise the cost-effective use of resources by concentrating them where appropriate;
- e to reinforce research, epidemiological surveillance like registries and provide training for health professionals;
- f to facilitate mobility of expertise, virtually or physically, and to develop, share and spread information, knowledge and best practice and to foster developments of the diagnosis and treatment of rare diseases, within and outside the networks;
- g to encourage the development of quality and safety benchmarks and to help develop and spread best practice within and outside the network;
- h to help Member States with an insufficient number of patients with a particular medical condition or lacking technology or expertise to provide highly specialised services of high quality.

3 Member States are encouraged to facilitate the development of the European reference networks:

- a by connecting appropriate healthcare providers and centres of expertise throughout their national territory and ensuring the dissemination of information towards appropriate healthcare providers and centres of expertise throughout their national territory;
- b by fostering the participation of healthcare providers and centres of expertise in the European reference networks.

4 For the purposes of paragraph 1, the Commission shall:

a adopt a list of specific criteria and conditions that the European reference networks must fulfil and the conditions and criteria required from healthcare providers wishing to join the European reference network. These criteria and conditions shall ensure, inter alia, that European reference networks:

(i) have knowledge and expertise to diagnose, follow-up and manage patients with evidence of good outcomes, as far as applicable;

(ii) follow a multi-disciplinary approach;

(iii) offer a high level of expertise and have the capacity to produce good practice guidelines and to implement outcome measures and quality control;

(iv) make a contribution to research;

(v) organise teaching and training activities; and

(vi) collaborate closely with other centres of expertise and networks at national and international level;

b develop and publish criteria for establishing and evaluating European reference networks;

c facilitate the exchange of information and expertise in relation to the establishment of European reference networks and their evaluation.

5 The Commission shall adopt the measures referred to in paragraph 4(a) by means of delegated acts in accordance with Article 17 and subject to the conditions of Articles 18 and 19. The measures referred to in points (b) and (c) of paragraph 4 shall be adopted in accordance with the regulatory procedure referred to in Article 16(2).

6 Measures adopted pursuant to this Article shall not harmonise any laws or regulations of the Member States and shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.