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 U.K.

COOPERATION IN HEALTHCARE

Article 10 *U.K.*

Mutual assistance and cooperation

1 Member States shall render such mutual assistance as is necessary for the implementation of this Directive, including cooperation on standards and guidelines on quality and safety and the exchange of information, especially between their national contact points in accordance with Article 6, including on provisions on supervision and mutual assistance to clarify the content of invoices.

2 Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level as well as through ICT and other forms of cross-border cooperation.

3 The Commission shall encourage Member States, particularly neighbouring countries, to conclude agreements among themselves. The Commission shall also encourage the Member States to cooperate in cross-border healthcare provision in border regions.

4 Member States of treatment shall ensure that information on the right to practise of health professionals listed in national or local registers established on their territory is, upon request, made available to the authorities of other Member States, for the purpose of cross-border healthcare, in accordance with Chapters II and III and with national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC, and the principle of presumption of innocence. The exchange of information shall take place via the Internal Market Information system established pursuant to Commission Decision 2008/49/EC of 12 December 2007 concerning the implementation of the Internal Market Information System (IMI) as regards the protection of personal data[(1)].

Article 11 *U.K.*

Recognition of prescriptions issued in another Member State

1 If a medicinal product is authorised to be marketed on their territory, in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004, Member States shall ensure that prescriptions issued for such a product in another Member State for a named patient can be dispensed on their territory in compliance with their national legislation in force, and that any restrictions on recognition of individual prescriptions are prohibited unless such restrictions are:

a limited to what is necessary and proportionate to safeguard human health, and non-discriminatory; or

b based on legitimate and justified doubts about the authenticity, content or comprehensibility of an individual prescription.

The recognition of such prescriptions shall not affect national rules governing prescribing and dispensing, if those rules are compatible with Union law, including

generic or other substitution. The recognition of prescriptions shall not affect the rules on reimbursement of medicinal products. Reimbursement of costs of medicinal products is covered by Chapter III of this Directive.

In particular, the recognition of prescriptions shall not affect a pharmacist's right, by virtue of national rules, to refuse, for ethical reasons, to dispense a product that was prescribed in another Member State, where the pharmacist would have the right to refuse to dispense, had the prescription been issued in the Member State of affiliation.

The Member State of affiliation shall take all necessary measures, in addition to the recognition of the prescription, in order to ensure continuity of treatment in cases where a prescription is issued in the Member State of treatment for medicinal products or medical devices available in the Member State of affiliation and where dispensing is sought in the Member State of affiliation.

This paragraph shall also apply to medical devices that are legally placed on the market in the respective Member State.

2 In order to facilitate implementation of paragraph 1, the Commission shall adopt:

a measures enabling a health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by a member of a regulated health profession who is legally entitled to do so through developing a non-exhaustive list of elements to be included in the prescriptions and which must be clearly identifiable in all prescription formats, including elements to facilitate, if needed, contact between the prescribing party and the dispensing party in order to contribute to a complete understanding of the treatment, in due respect of data protection;

b guidelines supporting the Member States in developing the interoperability of ePrescriptions;

c measures to facilitate the correct identification of medicinal products or medical devices prescribed in one Member State and dispensed in another, including measures to address patient safety concerns in relation to their substitution in cross border healthcare where the legislation of the dispensing Member State permits such substitution. The Commission shall consider, inter alia, using the International Non-proprietary Name and the dosage of medicinal products;

d measures to facilitate the comprehensibility of the information to patients concerning the prescription and the instructions included on the use of the product, including an indication of active substance and dosage.

Measures referred in point (a) shall be adopted by the Commission no later than 25 December 2012 and measures in points (c) and (d) shall be adopted by the Commission no later than 25 October 2012.

3 The measures and guidelines referred to in points (a) to (d) of paragraph 2 shall be adopted in accordance with the regulatory procedure referred to in Article 16(2).

4 In adopting measures or guidelines under paragraph 2, the Commission shall have regard to the proportionality of any costs of compliance with, as well as the likely benefits of, the measures or guidelines.

5 For the purpose of paragraph 1, the Commission shall also adopt, by means of delegated acts in accordance with Article 17 and subject to the conditions of Articles 18 and 19 and no later than 25 October 2012 measures to exclude specific categories of medicinal products or medical devices from the recognition of prescriptions provided for under this Article, where necessary in order to safeguard public health.

6 Paragraph 1 shall not apply to medicinal products subject to special medical prescription provided for in Article 71(2) of Directive 2001/83/EC.

Article 12 U.K.

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.

Article 13 U.K.

Rare diseases

The Commission shall support Member States in cooperating in the development of diagnosis and treatment capacity in particular by aiming to:

(a) make health professionals aware of the tools available to them at Union level to assist them in the correct diagnosis of rare diseases, in particular the Orphanet database, and the European reference networks;

(b) make patients, health professionals and those bodies responsible for the funding of healthcare aware of the possibilities offered by Regulation (EC) No 883/2004 for referral of patients with rare diseases to other Member States even for diagnosis and treatments which are not available in the Member State of affiliation.

Article 14 U.K.

eHealth

1 The Union shall support and facilitate cooperation and the exchange of information among Member States working within a voluntary network connecting national authorities responsible for eHealth designated by the Member States.

2 The objectives of the eHealth network shall be to:

a work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare;

b draw up guidelines on:

(i) a non-exhaustive list of data that are to be included in patients' summaries and that can be shared between health professionals to enable continuity of care and patient safety across borders; and

(ii) effective methods for enabling the use of medical information for public health and research;

c support Member States in developing common identification and authentication measures to facilitate transferability of data in cross-border healthcare.

The objectives referred to in points (b) and (c) shall be pursued in due observance of the principles of data protection as set out, in particular, in Directives 95/46/EC and 2002/58/EC.

3 The Commission shall, in accordance with the regulatory procedure referred to in Article 16(2), adopt the necessary measures for the establishment, management and transparent functioning of this network.

Article 15 U.K.

Cooperation on health technology assessment

1 The Union shall support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or bodies responsible for health technology assessment designated by the Member States. The Member States shall communicate their names and contact details to the Commission. The members of such a health technology assessment network shall participate in, and contribute to, the network's activities in accordance with the legislation of the Member State where they are established. That network shall be based on the principle of good governance including transparency, objectivity, independence of expertise, fairness of procedure and appropriate stakeholder consultations.

2 The objectives of the health technology assessment network shall be to:

a support cooperation between national authorities or bodies;

b support Member States in the provision of objective, reliable, timely, transparent, comparable and transferable information on the relative efficacy as well as on the short- and long-term effectiveness, when applicable, of health technologies and to enable an effective exchange of this information between the national authorities or bodies;

c support the analysis of the nature and type of information that can be exchanged;

d avoid duplication of assessments.

3 In order to fulfil the objectives set out in paragraph 2, the network on health technology assessment may receive Union aid. Aid may be granted in order to:

a contribute to the financing of administrative and technical support;

b support collaboration between Member States in developing and sharing methodologies for health technology assessment including relative effectiveness assessment;

c contribute to the financing of the provision of transferable scientific information for use in national reporting and case studies commissioned by the network;

d facilitate cooperation between the network and other relevant institutions and bodies of the Union;

e facilitate the consultation of stakeholders on the work of the network.

4 The Commission shall, in accordance with the regulatory procedure referred to in Article 16(2), adopt the necessary measures for the establishment, management and transparent functioning of this network.

5 Arrangements for granting the aid, the conditions to which it may be subject and the amount of the aid, shall be adopted in accordance with the regulatory procedure referred to in Article 16(2). Only those authorities and bodies in the network designated as beneficiaries by the participating Member States shall be eligible for Union aid.

6 The appropriations required for measures provided for in this Article shall be decided each year as part of the budgetary procedure.

7 Measures adopted pursuant to this Article shall not interfere with Member States' competences in deciding on the implementation of health technology assessment conclusions and 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.

(**1**) OJ L 13, 16.1.2008, p. 18.