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from: Presidency

to: Council

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Subject: **COUNCIL MEETING (EMPLOYMENT, SOCIAL POLICY, HEALTH
AND CONSUMERS AFFAIRS) ON 7 AND 8 JUNE 2010**

Legislative deliberations

(public deliberation in accordance with Article 16(8) of the Treaty on the European Union)

Proposal for a Directive of the European Parliament and of the Council on the application of **patients' rights** in cross-border healthcare (*)

(Legal basis proposed by the Commission: Article 114 of the TFEU)

- Political agreement

1. On 2 July 2008, the European Commission presented a proposal for a Directive on patient's rights in cross-border healthcare. The proposal was based on Article 95 of the Treaty establishing the European Community (Article 114 of the Treaty on the Functioning of the European Union), and it is subject to both qualified majority in Council and ordinary procedure with the European Parliament. The draft Directive aims to facilitate the access to safe and high-quality cross-border healthcare and promotes cooperation on healthcare between Member States, in full respect of national competencies in organising and delivering healthcare.

2. On 23 April 2008 the European Parliament (EP) adopted its first reading opinion¹, approving 122 amendments to the original Commission's proposal. The Economic and Social Committee delivered its opinion on 4 December 2008² and the Committee of the Regions on 12 February 2009³. The European Data Protection Supervisor delivered its opinion on 2 December 2008⁴.
3. Despite the substantial progress made by the French, Czech and Swedish Presidencies, the Council (EPSCO) was unable to reach a political agreement on this proposal on 1 December 2009. The discussions in the Council focused mainly on the reimbursement of costs with regard to non-contractual healthcare providers and on pensioners living abroad. The Spanish Presidency committed at this meeting to make every effort to obtain an agreement in the Council during its term.
4. As the previous Presidencies, the Spanish Presidency's objective is to strike the right balance between the rights of the patients in cross-border healthcare and the responsibilities of the Member States for the organisation and delivery of health services and medical care. In addition, the Directive should supplement the rights that patients already have at the EU level through the legislation on the coordination of social security schemes.
5. The Council will find in the Annex a new Presidency's compromise text for this proposal. This compromise contains new solutions for the issues that remained open after the Council of 1 December 2009:
 - Reimbursement and prior authorisation with regard to non-contractual healthcare providers (Article 8.3a, 9.2(c) and 9.4(e));
 - Member State of affiliation with regard to pensioners living abroad (Article 8.1a).

¹ Doc. 8903/09.

² SOC/322 - CESE 1927/2008.

³ CdR 348/2008 fin - DEVE-IV-032.

⁴ Doc. 16855/08.

6. In addition to this and following consultations with the delegations and the Commission and examination by the Working Party on Public Health and the Permanent Representatives Committee of previous texts from the Presidency, the Presidency proposes:
- a double legal basis for the Directive (i.e. Articles 114 and 168 of the TFUE);
 - reinforcement of the provisions on e-Health (Article 14).
7. The Council is invited to consider the text proposed in the annex of this note with the view of reaching a political agreement on a common position that should allow for the second reading in the EP in order to have this Directive adopted as soon as possible.

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the application of patients' rights in cross-border healthcare

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the functioning of the European Union, and in particular Articles 114 and 168 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

After consulting the European Data Protection Supervisor,

Acting in accordance with the procedure laid down in Article 294 of the Treaty,

Whereas:

- (1) According to Article 168(1) of the Treaty, a high level of human health protection must be ensured in the definition and implementation of all Union policies and activities. This implies that a high level of human health protection has to be ensured also when the Union adopts acts under other Treaty provisions.
- (2) For the majority of the provisions in this Directive, Article 114 of the Treaty is the appropriate legal base since the provisions have the aim of improving the functioning of the internal market and the free movement of goods, services and persons. Given that the conditions for recourse to Article 114 of the Treaty as a legal basis are fulfilled, the Union legislation shall rely on this legal basis even when public health protection is a decisive factor in the choices made; in this respect Article 114(3) of the Treaty explicitly requires that, in achieving harmonisation, a high level of protection of human health should be guaranteed taking account in particular of any new development based on scientific facts.

- (3) The health systems of the Union are a central component of Europe’s high levels of social protection, and contribute to social cohesion and social justice as well as to sustainable development. They are also part of the wider framework of services of general interest.
- (3a) As recognised by the Member States in the Council Conclusions of 1-2 June 2006 on “Common values and principles in European Union Health Systems” there is a set of operating principles that are shared by health systems throughout the Union. In the same statement, the Council recognized that the practical ways in which these values and principles become a reality vary significantly between Member States. In particular, decisions about the basket of healthcare to which citizens are entitled and the mechanisms used to finance and deliver that healthcare, such as the extent to which it is appropriate to rely on market mechanisms and competitive pressures to manage health systems must be taken in the national context.
- (4) As confirmed by the Court of Justice on several occasions, while recognizing their specific nature, all types of medical care fall within the scope of the Treaty.
- (5) Some issues related to cross-border healthcare, in particular reimbursement of healthcare provided in a Member State other than that in which the recipient of the care is resident, have been already addressed by the Court of Justice. As healthcare was excluded from the scope of Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market it is important to address these issues in a specific Union legal instrument in order to achieve a more general and effective application of principles developed by the Court of Justice on a case by case basis.
- (6) In the Council Conclusions on Common values and principles in European Union Health Systems the Council recognised particular value of an initiative on cross-border healthcare ensuring clarity for European citizens about their rights and entitlements when they move from one Member State to another in order to ensure legal certainty.

- (7) This Directive aims to establish rules for facilitating the access to safe and high quality cross-border healthcare in the Union and to ensure patients mobility in accordance with the principles established by the Court of Justice and to promote cooperation on healthcare between Member States, whilst fully respecting the responsibilities of the Member States for the definition of social security benefits related to health and the organisation and delivery of healthcare and medical care and social security benefits in particular for sickness.
- (8) This Directive on the application of patients' rights in cross-border healthcare applies to individual patients who decide to seek healthcare in a Member State other than the Member State of affiliation. As confirmed by the Court of Justice, neither its special nature nor the way in which it is organised or financed removes healthcare from the ambit of the fundamental principle of freedom to provide services. However, the Member State of affiliation may choose to limit the reimbursement of cross-border healthcare for reasons relating to the quality and safety of the healthcare provided where this can be justified by overriding reasons of general interest related to public health. The Member State of affiliation may also make further provisions on other grounds where this can be justified by such overriding reasons of general interest. Indeed, the Court of Justice has laid down that public health protection is among the overriding reasons of general interest that can justify restrictions to the freedom of movement envisaged in the Treaties.

- (8aa) The concept of “overriding reasons of general interest” to which reference is made in certain provisions of this Directive has been developed by the Court of Justice in its case law in relation to Articles 49 and 56 of the Treaty and may continue to evolve. The Court has held on a number of occasions that it is possible for the risk of seriously undermining the financial balance of a social security system to constitute per se an overriding reason in the general interest capable of justifying an obstacle to the freedom to provide services. The Court has likewise acknowledged that the objective of maintaining on grounds of public health a balanced medical and hospital service open to all may also fall within one of the derogations, on grounds of public health, provided for in Article 52 of the Treaty in so far as it contributes to the attainment of a high level of health protection. The Court has also held that that provision of the Treaty permits Member States to restrict the freedom to provide medical and hospital services in so far as the maintenance of treatment capacity or medical competence on national territory is essential for public health.
- (8a) In this Directive, healthcare means all health services provided by health professionals to patients to assess, maintain or restore their state of health. However, it is clear that the obligation to reimburse costs of cross-border healthcare shall be limited to healthcare for which the insured person is entitled to according to the legislation of his/her Member State of affiliation.
- (8b) This Directive does not apply to services whose primary purpose is to support people in need of assistance in carrying out routine, everyday tasks. More specifically this refers to those long-term care services deemed necessary in order to enable the person in need of care to live as full and self-determined life as possible. Thus, this Directive should not apply, for example, to long-term care services provided in residential homes or housing (“nursing homes”), by home care services or in assisted living facilities.
- (8c) Given its specificity, the access to and allocation of organs for the purpose of organ transplants should fall outside the scope of this Directive.

- (9) For the purpose of reimbursing cross-border healthcare, this Directive should cover not only the situation where the patient receives healthcare provided in a Member State other than the Member State of affiliation; but also the prescription, dispensation and provision of medicinal products and medical devices when these are provided in the context of a health service. The definition of cross-border healthcare should cover both the situation when a patient purchases such medicinal products and medical devices in a Member State other than the Member State of affiliation and the situation when the patient purchases such medicinal products and medical devices in another Member State than that where the prescription was issued.
- (9aa) This Directive does not affect Member States rules concerning sales of medicinal products and medical devices over the Internet.
- (9a) This Directive does not give any person an entitlement to enter, stay or reside in a Member State in order to receive healthcare in that State. In case that the stay of a person on the territory of a Member State is not in accordance with the legislation of that Member State concerning the right to enter or stay on its territory, such person is not regarded as an insured person according to the definition in this Directive. It continues to be for Member States to define in their national legislation who is considered as an insured person for the purposes of their public healthcare scheme and social security legislation as long as the patients' rights enacted in this Directive are secured.
- (10) When a patient receives cross-border healthcare, it is essential for the patient to know in advance which rules will be applicable. In those cases, the rules applicable to healthcare are those provided by the legislation of the Member State of treatment, given that in accordance with Art. 168(7) of the Treaty the organisation and delivery of health services and medical care is of responsibility of Member States. This will help the patient in making an informed choice, and will avoid misapprehension and misunderstanding. It will also establish a high level of trust between the patient and the healthcare provider.

- (11) In order to enable patients to make an informed choice when they seek to receive healthcare in another Member State, the Member State of treatment shall ensure that patients from other Member States receive on request the relevant information on safety and quality standards enforced on its territory as well as on which healthcare providers that are subject to these standards. Furthermore, healthcare providers should provide patients on request with information on several aspects of the healthcare services they offer. To the extent that healthcare providers already provide patients resident in the Member State of treatment with relevant information on these subjects, this Directive does not oblige healthcare providers to provide more extensive information to patients from other Member States. Nothing prevents the Member State of treatment from also obliging other actors than the healthcare providers, such as insurance providers or public authorities, to provide this information if this is more suitable with regard to the organisation of its healthcare system.
- (11a) Member States should ensure that all patients are treated equitably on the basis of their healthcare need rather than their Member State of affiliation. In doing so, Member States should respect the principles of free movement of persons within the internal market, non-discrimination inter alia with regard to nationality and necessity and proportionality of any restrictions on free movement. However, nothing in this Directive requires healthcare providers to accept for planned treatment or to prioritise patients from other Member States to the detriment of other patients, such as through increasing waiting time for treatment. Inflows of patients may create a demand exceeding the capacities existing in a Member State for a given healthcare. In such exceptional cases, the Member State should retain the possibility to remedy the situation on the grounds of public health, in accordance with Articles 52 and 62 of the Treaty. However this limitation is without prejudice to the Member States obligations under Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems.
- (12a) Systematic and continuous efforts should be made to ensure that quality and safety standards are improved in line with the Council Conclusions of 1-2 June 2006 on Common Values and Principles in European Union Health Systems and taking into account advances in international medical science and generally recognized good medical practices.

- (13) Ensuring clear common obligations to deal with circumstances of responding to harm arising from healthcare is essential to avoid lack of confidence in those mechanisms acting as an obstacle to taking up cross-border healthcare. Systems for addressing harm in the Member State of treatment should be without prejudice to the possibility for Member States to extend the coverage of their domestic systems to patients from their country seeking healthcare abroad, where this is more appropriate to the patient.
- (14) Member States should ensure, that mechanisms for the protection of patients and for seeking remedies in the event of harm are in place for healthcare provided on their territory and that they are appropriate to the nature and extent of the risk. However, it is for the Member State to determine the nature and/or modalities of such a mechanism.
- (15) The right to the protection of personal data is a fundamental right recognised by Article 8 of the Charter of Fundamental Rights of the European Union. Ensuring continuity of cross-border healthcare depends on transfer of personal data concerning patient's health. These personal data should be able to flow freely from one Member State to another, but in the same time the fundamental rights of the individuals should be safeguarded. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data establishes the right for individuals to have access to their personal data concerning their health, for example in the patient's medical records containing such matters as diagnosis, examination results, assessments by treating physicians and any treatment or interventions provided. These provisions also apply in the context of cross-border healthcare covered by this Directive.

- (16) The right to reimbursement of the costs of healthcare provided in another Member State from the statutory social security scheme of patients as insured persons was recognised by the Court of Justice in several judgements. The Court of Justice has held that the Treaty provisions on the freedom to provide services includes the freedom for the recipients of healthcare, including persons in need of medical treatment, to go to another Member State in order to receive it there. The same applies to recipients of healthcare seeking to receive healthcare provided in another Member State through other means, for example through e-health services.
- (17) In accordance with the principles established by the Court of Justice, and without endangering the financial balance of Member States' healthcare and social security systems, greater legal certainty as regards the reimbursement of healthcare costs should be provided for patients and for health professionals, healthcare providers and social security institutions.
- (18) This Directive does not affect patient's rights to the assumption of costs of healthcare which become necessary on medical grounds during a temporary stay of insured persons in another Member State according to Article 19 of Regulation (EC) No 883/2004. Neither does this Directive affect patient's rights to be granted an authorisation for a treatment in another Member State where the conditions provided for by Union Regulations on coordination of social security schemes, in particular Article 22 of Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community which is applicable by virtue of Council Regulation (EC) No 859/2003 of 14 May 2003 extending the provisions of Regulation (EEC) No 1408/71 and Regulation (EEC) No 574/72 to nationals of third countries who are not already covered by those provisions solely on the ground of their nationality, and Article 20 of Regulation (EC) No 883/2004 are met.

- (19) It is appropriate to require that also patients who go for healthcare to another Member State in other circumstances than those envisaged for coordination of social security schemes established by the Regulations (EEC) No. 883/2004 should be able to benefit from the principles of free movement of services in accordance with the Treaty and the provisions of this Directive. Patients should be guaranteed assumption of the costs of that healthcare at least at the level provided for the same healthcare had they it been provided in the Member State of affiliation. This fully respects responsibility of the Member States to determine the extent of the sickness cover available to their citizens and prevents any significant effect on the financing of the national healthcare systems.
- (20) For the patient, therefore, the two systems are coherent; either this Directive applies or the Union Regulations on coordination of social security schemes.
- (21) The patient should not be deprived of the more beneficial rights guaranteed by the Regulations (EC) on coordination of social security systems when the conditions are met. Therefore, any patient who requests an authorisation to receive a treatment appropriate to his/her condition in another Member State shall always be granted this authorisation under the conditions provided for in the Union Regulations when the treatment in question is among the benefits provided for by the legislation in the Member State where the patient resides and when the patient cannot be given such treatment within the time medically justifiable, taking account of his/her current state of health and the probable course of the disease. However, if a patient instead explicitly requests to seek treatment under the terms of the Directive, the benefits which apply to reimbursement will be limited to those which apply under the Directive.
- (22) The patient should, in any event, not derive a financial advantage from the healthcare provided in another Member State and the assumption of costs should be therefore limited only to actual costs of healthcare received.

- (23) This Directive does not aim to create entitlement for reimbursement of cost of healthcare provided in another Member State, if such healthcare is not among the benefits provided for by the legislation of the Member State of affiliation of the insured person. Equally, this Directive does not prevent the Member States from extending their benefits in kind scheme to healthcare provided in another Member State according to its provisions. This Directive recognises that Member States are free to organise their own healthcare and social security systems in such a way as to determine entitlement for treatment at a regional or local level.
- (24) This Directive does not provide either for transfer of social security entitlements between Member States or other coordination of social security schemes. The sole objective of the provisions regarding prior authorisation and reimbursement of healthcare provided in another Member State is to enable freedom to provide healthcare for patients and to remove unjustified obstacles to that fundamental freedom within the patient's Member State of affiliation. Consequently the Directive fully respects the differences of national healthcare systems and the Member States' responsibilities for organisation and delivery of health services and medical care.
- (25) This Directive provides for the right for a patient to receive any medicinal product authorised for marketing in the Member State of treatment, even if the medicinal product is not authorised for marketing in the Member State of affiliation, as it is an indispensable part of obtaining effective treatment in another Member State. Nothing obliges a Member State of affiliation to reimburse an insured person for a medicinal product prescribed in the Member State of treatment, which is not among the benefits provided to that insured person by the statutory social security system or national health system in the Member State of affiliation.

(26) Member States may maintain general conditions, criteria for eligibility and regulatory and administrative formalities for receipt of healthcare and reimbursement of healthcare costs, such as the requirement to consult a general practitioner before consulting a specialist or before receiving hospital care, also in relation to patients seeking healthcare in another Member State provided that such conditions are necessary, proportionate to the aim and are not discretionary and discriminatory. This may include an assessment by a health professional or healthcare administrator providing services for the statutory social security system or national health system of the Member State of affiliation, such as the general practitioner or primary care practitioner with whom the patient is registered, if this is necessary for determining the individual patient's entitlement to healthcare. It is thus appropriate to require that these general conditions and formalities are being applied in an objective, transparent and non-discriminatory way and are known in advance, based primarily on medical considerations and that they do not impose any additional burden on patients seeking healthcare in another Member State in comparison with patients being treated in their Member State of affiliation, and that decisions are made as quickly as possible. This is without prejudice to the rights of the Member States to provide for criteria or conditions of prior authorisation in the case of patients seeking healthcare in their Member State of affiliation. Since conditions, criteria and formalities relating to entitlements to healthcare, such as determining the cost-effectiveness of a specific treatment, is a matter for the Member State of affiliation, such conditions, criteria and formalities cannot be required in the Member State of treatment as well as this would constitute an obstacle to the free movement of persons, goods and services. However, the Member State of treatment may impose conditions, criteria and formalities relating to clinical circumstances, such as assessing patient safety risks in performing a specific procedure on a specific patient. Furthermore, these conditions, criteria and formalities could include a procedure that ensures that a person seeking healthcare in another Member State understands that the healthcare received will be subject to laws and regulations of the Member State of treatment, including standards on quality and safety and other standards required by that Member State, and that this person has been provided with all technical, professional and medical support required for making an informed choice of healthcare provider, if this procedure is neither discriminatory nor an obstacle to the free movement of persons, services or goods.

- (27) In the light of the case-law of the Court of Justice, making the assumption by the statutory social security system or national health system of costs of healthcare provided in another Member State subject to prior authorisation is a restriction to free movement of services. Therefore, as a general rule, the Member State of affiliation should not make the assumption of the costs healthcare provided in another Member State subject to prior authorisation, where the costs of that care, if it had been provided in its territory, would have been paid for by its statutory social security system or national health system.
- (28) According to the constant case-law of the Court of Justice, Member States may make the assumption of costs by the national system of hospital care provided in another Member State subject to prior authorisation. The Court has judged that this requirement is both necessary and reasonable, since the number of hospitals, their geographical distribution, the way in which they are organised and the facilities with which they are provided, and even the nature of the medical services which they are able to offer, are all matters for which planning, generally designed to satisfy various needs, must be possible. The Court has found that for one thing, such planning seeks to ensure that there is sufficient and permanent access to a balanced range of high-quality hospital treatment in the Member State concerned. For another thing, it assists in meeting a desire to control costs and to prevent, as far as possible, any wastage of financial, technical and human resources. According to the Court, such wastage would be all the more damaging because it is generally recognised that the hospital care sector generates considerable costs and must satisfy increasing needs, while the financial resources which may be made available for healthcare are not unlimited, whatever the mode of funding applied.
- (29a) The same reasoning applies to healthcare not provided in a hospital but subjected to similar planning needs in the Member State of treatment. This may be healthcare which requires planning because it involves use of highly specialised and cost-intensive medical infrastructure or medical equipment. With regard to the progress of technology, the development of new methods of treatment and the different policies of Member States regarding the roles of hospitals in their healthcare systems, whether this kind of healthcare is delivered within hospital or ambulatory care facilities is not the decisive factor for deciding whether it requires planning or not.

(29b) Given that the Member States are responsible for laying down rules as far as the management, the requirements, the quality and safety standards and the organisation and delivery of healthcare and that the planning necessities differ from one Member State to another, it is therefore for the Member States to decide whether there is a need to introduce the system of prior authorisation, and if so, to identify the healthcare requiring prior authorisation in the context of their system in accordance with the criteria defined by this Directive and in the light of the case law of the Court of Justice. The information concerning this care shall be made publicly available for all the patients.

(29c) The criteria attached to the grant of prior authorisation should be justified in the light of the overriding reasons in the general interest capable of justifying obstacles to the free movement of healthcare. The Court of Justice has identified several potential considerations: the risk of seriously undermining the financial balance of a social security system, the objective of maintaining on grounds of public health a balanced medical and hospital service open to all or the objective of maintaining treatment capacity or medical competence on national territory, essential for the public health, and even the survival of the population. It is also important to take in consideration the general principle of protecting the safety of the patient in a sector well known by information asymmetry when managing a prior authorization system. Conversely, the refusal to grant prior authorisation may not be based solely on the ground that there are waiting lists on national territory intended to enable the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out an objective medical assessment of the patient's medical condition, the history and probable course of his illness, the degree of pain he/she is in and/ or the nature of his disability at the time when the request for authorisation was made or renewed.

(29d) According to the constant case-law of the Court of Justice, the criteria for granting or refusing prior authorisation shall be limited to what is necessary and proportionate in the light of these overriding reasons in the general interest. It should be noted that the impact on national health systems caused by patient mobility might vary between Member States or between regions within a Member State, depending on factors such as geographical location, language barriers, location of hospitals in border regions or the size of the population and/or healthcare budget. Therefore it should be for every Member State to set up such criteria for refusing prior authorisation that are necessary and proportionate in that specific context, also taking into account which healthcare falls within the scope of the prior authorisation system since certain treatments of a highly specialised nature will be more easily affected even by a limited patient outflow than others. Therefore, Member States should be able to set up different criteria for different regions or other relevant administrative levels for the organisation of healthcare, or indeed for different treatments, as long as the system is transparent and easily accessible and the criteria are made public in advance.

(30) In any event, if a Member State decided to establish a system of prior authorisation for assumption of costs of hospital or specialised care provided in another Member State in accordance with the provision of this Directive, the costs of such care provided in another Member State should also be reimbursed by the Member State of affiliation up to the level of costs that would have been assumed had the same healthcare been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received. However, when the conditions set out in Article 22(2) of Regulation (EEC) No 1408/71 or Article 20 of Regulation (EC) No 883/2004 are fulfilled the authorisation should be granted and the benefits provided in accordance with those Regulations unless otherwise requested by the patient. This applies in particular in instances where the authorisation is granted after an administrative or judicial review of the request and the person concerned has received the treatment in another Member State. In that case Articles, 8 and 9 of this Directive shall not apply. This is in line with the case law of the Court of Justice which has specified that patients who received a refusal of authorisation subsequently held to be unfounded, are entitled to have the cost of the treatment obtained in another Member State reimbursed in full according to the provisions of the legislation in the Member State of treatment.

- (31) Procedures regarding cross-border healthcare established by the Member States should give patients guarantees of objectivity, non discrimination and transparency, in such a way as to ensure that decisions by national authorities are made in a timely manner and with due care and regard for both those overall principles and the individual circumstances of each case. This applies also to the actual reimbursement of costs of healthcare incurred in another Member State after the patient has received treatment.
- (32) Appropriate information on all essential aspects of cross-border healthcare is necessary in order to enable patients to exercise their rights on cross-border healthcare in practice. For cross-border healthcare one of the mechanisms for providing such information is to establish national contact points within each Member State. Information that have to be provided compulsorily to patients are specified, however the national contact points may provide more information voluntarily and also with the support of the European Commission. Information shall be provided for by national contact points to patients in any of the official languages of the Member State in which the contact points are situated. Information may, but does not have to, be provided also in languages other than in the official languages of the Member State in which the national contact points are situated.
- (33) The Member States should decide on the form of those national contact points as well as the number of them. The national contact points may also be incorporated in or build on activities of existing information centres provided that it is clearly indicated that they are also national contact points for cross-border healthcare. The national contact points should have appropriate facilities to provide information on the main aspects of cross-border healthcare. The Commission should work together with the Member States in order to facilitate cooperation regarding national contact points for cross-border healthcare, including making relevant information available at Union level. The existence of national contact points should not preclude Member States from establishing other linked contact points at regional or local level, reflecting the specific organisation of their healthcare system.

- (34) Member States should facilitate cooperation between providers, purchasers and regulators of different Member States at national, regional or local level in order to ensure safe, high quality and efficient care across borders. This could be of particular importance in border regions, where cross-border provision of services may be the most efficient way of organising health services for the local populations, but where achieving such cross-border provision on a sustained basis requires cooperation between the health systems of different Member States. Such cooperation may concern joint planning, mutual recognition or adaptation of procedures or standards, interoperability of respective national information and communication technology systems, practical mechanisms to ensure continuity of care or practical facilitating of cross-border provision of healthcare by health professionals on a temporary or occasional basis. Directive 2005/36/EC of the European Parliament and of the Council of 24 October 1995 on the recognition of professional qualifications stipulates that free provision of services of a temporary or occasional nature, including services provided by health professionals, in another Member State should not, subject to specific provisions of Union law, be restricted for any reason relating to professional qualifications. This Directive should be without prejudice to those provisions of Directive 2005/36/EC.
- (35) The Commission should encourage cooperation between the Member States in the areas set out in Chapter IV of this Directive and may, in accordance with Article 168.2 Treaty on the functioning of the European Union, take, in close contact with the Member States, any useful initiative to facilitate and promote such cooperation.

(36) Where medicinal products are authorised within a Member State and have been prescribed in another Member State by a member of a regulated health profession within the meaning of Article 3(1)(a) of Directive 2005/36/EC for an individual named patient, it should be in principle possible for such prescriptions to be medically recognised and dispensed in the former Member State. The removal of regulatory and administrative barriers to such recognition is without prejudice to the need for appropriate agreement of the patients' treating physician or pharmacist in every individual case, if this is warranted by protection of human health and is necessary and proportionate to that objective. The recognition of prescriptions from other Member States shall not affect any professional or ethical duty that would require the pharmacist to refuse to dispense the prescription. Such medical recognition should also be without prejudice to the decision of the Member State of affiliation regarding the inclusion of such medicinal products within the benefits covered by the social security system of affiliation. It should further be noted that the reimbursement of medicinal products is not affected by the rules on mutual recognition of prescriptions, but covered by the general rules on reimbursement of cross-border healthcare in Chapter III of this Directive. The implementation of the principle of recognition will be facilitated by the adoption of measures necessary for safeguarding the safety of a patient, and avoiding the misuse or confusion of medicinal products. These measures include the adoption of a non-exhaustive list of elements to be included in prescriptions. Nothing prevents Member States from having further elements in their prescriptions, as long as this does not prevent prescriptions from other Member States that contain the common list of elements from being recognised. The recognition of prescriptions should also apply for medical devices that are legally placed on the market in the Member State where the device will be dispensed.

- (37) The Commission should support the continued development of European reference networks between healthcare providers and centres of expertise in the Member States. European reference networks can improve the access to diagnosis and the provision of high-quality healthcare to all patients who have conditions requiring a particular concentration of resources or expertise, and could also be focal points for medical training and research, information dissemination and evaluation. Therefore, this Directive should give incentives to Member States to facilitate the continued development of European reference networks. The European reference networks are based on voluntary participation by its members, but the Commission should develop criteria and conditions that the networks should fulfil in order to receive support from the Commission.
- (38) Technological developments in cross-border provision of healthcare through the use of information and communication technologies may result in the exercise of supervisory responsibilities by Member States being unclear, and thus can hinder the free movement of healthcare and give rise to possible additional risks to health protection through this mode of supply. Widely different and incompatible formats and standards are used for cross-border provision of healthcare using information and communication technologies throughout the Union, creating both obstacles to this mode of cross-border healthcare provision and possible risks to health protection. It is therefore necessary for Member States to aim at interoperability of ICT systems.
- (39) The constant progress of medical science and health technologies presents both opportunities and challenges to the health systems of the Member States. Cooperation in the evaluation of new health technologies can support Member States through economies of scale and avoiding duplication of effort, and provide a better basis of evidence for optimal use of new technologies to ensure safe, high-quality and efficient healthcare. Such cooperation requires sustained structures involving all the relevant authorities of the Member States, building on existing pilot projects. Therefore, this Directive should provide a basis for continued Union support for such cooperation.

(40) According to Article 291 of the Treaty, rules and general principles concerning mechanisms for the control by Member States of the Commission's exercise of implementing powers shall be laid down in advance by a regulation adopted in accordance with the ordinary legislative procedure. Pending the adoption of that new regulation, Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission continues to apply, with the exception of the regulatory procedure with scrutiny, which is not applicable.

(40a) The Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty in respect of measures that would:

- exclude specific categories of medicinal products or medical devices from the recognition of prescriptions, as provided for in this Directive;
- set out a non-exhaustive list of essential data to be included in Electronic Health Records and that can be shared between health professionals to enable continuity of care and patient safety across borders as well as a technical framework to enable use of medical information for public health and research;

(40b) It is of particular importance that, when empowered to adopt delegated acts in accordance with Article 290 of the Treaty, the Commission carries out appropriate consultations during its preparatory work, including at experts' level.

(41a) In accordance with point 34 of the Interinstitutional Agreement on better law-making, Member States are encouraged to draw up, for themselves and in the interests of the Union, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public.

(42) Since the objectives of this Directive, namely providing rules for facilitating the access to safe and high quality cross- border healthcare in the European Union, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives.

HAVE ADOPTED THIS DIRECTIVE

CHAPTER I

GENERAL PROVISIONS

Article 1

Aim

This Directive provides for rules for facilitating the access to safe and high-quality cross-border healthcare and promotes cooperation on healthcare between Member States, in full respect of national competencies in organising and delivering healthcare.

Article 2

Scope

1. This Directive shall apply to the provision of healthcare to patients, regardless of how it is organised, delivered and financed.
2. This Directive shall not apply to:
 - (a) services in the field of long-term care whose purpose is to support people in need of assistance in carrying out routine, everyday tasks;
 - (b) allocation and access to organs for the purpose of-organ transplants;

- © with the exception of Chapter IV; public vaccination programmes against infectious diseases, exclusively aimed at protecting the health of the population on the territory of a Member State and which are subject to specific planning and implementation measures.
3. This Directive shall not affect laws and regulations in Member States relating to the organisation and financing of healthcare in situations not related to cross-border healthcare. In particular, nothing in this Directive will oblige a Member State to reimburse costs of healthcare provided by healthcare providers established on its own territory if this provider is not part of the social security system or public health system of that Member State.

Article 3

Relationship with other Union provisions

This Directive shall apply without prejudice to:

- (a) Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications;
- (b) Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market;
- © Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector;

- (d) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;
- (da) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use;
- (db) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.
- (e) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use;
- (ea) Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems;
- (f) Directive 96/71/EC of the European Parliament and of the Council of 16 December 1996 concerning the posting of workers in the framework of the provision of services;
- (g) Council Directive 2000/43/EC of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin;
- (h) Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems and its implementing Regulation;
- (i) Regulation (EC) No 1338/2008 of the European Parliament and of the Council on Community statistics on public health and health and safety at work;

- (j) Regulation (EC) 1082/2006 of the European Parliament and of the Council of 5 July 2006 on a European Grouping of territorial cooperation (EGTC);
- (k) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC;
- (l) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells;
- (m) Council Regulation (EC) No 859/2003 of 14 May 2003 extending the provisions of Regulation (EEC) No 1408/71 and Regulation (EEC) No 574/72 to nationals of third countries who are not already covered by those provisions solely on the ground of their nationality.
- (n) Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I), Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II) and other Community rules on private international law, in particular rules related to court jurisdiction and the applicable law.

Article 4

Definitions

For the purposes of this Directive, the following definitions shall apply:

- (a) "healthcare" means health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices;

- (b) "insured person" means:
1. persons, including members of their families and their survivors, covered by Article 2 of Regulation (EC) No 883/2004 and who are insured within the meaning of Article 1© of that Regulation, and
 2. nationals of a third country who are covered by Regulation (EC) No 859/2003, or who satisfies the conditions of the legislation of the Member State of affiliation for entitlement to benefits.
- © "Member State of affiliation" means:
1. for persons referred to in the first paragraph of Article 4(b); the Member State that is competent to grant, to the insured person, a prior authorisation to receive appropriate treatment outside the Member State of residence according to Regulation (EC) No 883/2004 and its implementing Regulation.
 2. for persons referred to in the second paragraph of Article 4(b); the Member State that is competent to grant, to the insured person, a prior authorisation to receive appropriate treatment in another Member State according to Regulation (EC) No 859/2003. If no Member State is competent according to this Regulation, the Member State of affiliation shall be the Member State where the person is insured or has the rights to sickness benefits according to the legislation of that Member State.
- (d) "Member State of treatment" means the Member State on whose territory healthcare is actually provided to the patient. In the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established;
- (e) "cross-border healthcare" means healthcare provided or prescribed in a Member State other than the Member State of affiliation;

- (f) "health professional" means a doctor of medicine or a nurse responsible for general care or a dental practitioner or a midwife or a pharmacist within the meaning of Directive 2005/36/EC or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC or a person considered to be a health professional according to the legislation of the Member State of treatment;
- (g) "healthcare provider" means any natural or legal person or any other entity legally providing healthcare on the territory of a Member State;
- (h) "patient" means any natural person who seeks to receive or receives healthcare in a Member State;
- (i) "medicinal product" means a medicinal product as defined by Directive 2001/83/EC;
- (j) "medical device" means a medical device as defined by Council Directive 93/42/EEC of 14 June 1993 concerning medical devices or by Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices or by Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices;
- (k) "prescription" means a prescription for a medicinal product or a prescription for a medical device issued by a member of a regulated health profession within the meaning of Article 3(1)(a) of Directive 2005/36/EC legally entitled to do so in the Member State in which the prescription is issued;
- (l) "health technology" means a medicinal product or a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare.
- (m) "medical records" means all the documents containing data, assessments and information of any kind on a patient's situation and clinical development throughout the care process.

CHAPTER II

RESPONSIBILITIES OF MEMBER STATES WITH REGARDS TO CROSS-BORDER HEALTH CARE

Article 5

Responsibilities of the Member State of treatment

1. Cross-border healthcare shall be provided in accordance with the legislation of the Member State of treatment and according to standards and guidelines on quality and safety defined by that Member State.
2. The Member State of treatment shall ensure that:
 - (a) patients receive upon request relevant information on standards and guidelines referred to in paragraph 1, including provisions on supervision and assessment of healthcare providers, and information on which healthcare providers are subject to these standards and guidelines;
 - (b) Healthcare providers provide individual patients with relevant information on availability, quality and safety of the healthcare they provide in the Member State of treatment, transparent invoices and transparent information on prices, as well as on the healthcare providers' authorisation or registration status, their insurance cover or other means of personal or collective protection with regard to professional liability. To the extent that healthcare providers already provide patients resident in the Member State of treatment with relevant information on these subjects, this Directive does not oblige healthcare providers to provide more extensive information to patients from other Member States;
 - © there are systems in place of making complaints and mechanisms in place for patients to seek remedies in accordance with the legislation of the Member State of treatment if they suffer harm arising from the healthcare they receive;

- (d) systems of professional liability insurance or a guarantee or similar arrangement, which are equivalent or essentially comparable as regards their purpose and which are appropriate to the nature and the extent of the risk, are in place for treatment provided on its territory;
- (e) the fundamental right to privacy with respect to the processing of personal data is protected in conformity with national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC;
- (f) patients who have received treatment are entitled to a written or electronic medical record of such treatment, and access to at least a copy of this record in conformity with and subject to national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.

3. The principle of non-discrimination with regard to nationality shall be applied to patients from other Member States.

This shall be without prejudice to the possibility for the Member State of treatment, where it is justified by overriding reasons of general interest, to adopt measures regarding the access to treatment aimed at fulfilling its fundamental responsibility to ensure sufficient and permanent access to healthcare within its territory. Such measures shall be limited to what is necessary and proportionate and shall not constitute a means of arbitrary discrimination.

4. Member States shall ensure that healthcare providers apply to patients from other Member States the same scale of fees for healthcare that is paid for domestic patients in a comparable situation in the Member State of treatment, or charge a price calculated according to objective, non-discriminatory criteria if there is no comparable price for domestic patients.

This paragraph shall be without prejudice to national legislation which allows healthcare providers to set their own prices, provided that they do not discriminate against patients from other Member States.

5. This Directive does not affect laws and regulations in Member States on the use of languages, nor does it imply any obligation to deliver information in other languages than those which are official languages in the concerned Member State.

Article 6

Responsibilities of the Member State of affiliation

1. The Member State of affiliation shall ensure that cost of cross-border healthcare is reimbursed in accordance with Chapter III.
2. The Member State of affiliation shall ensure that there are mechanisms in place to provide patients on request with information on their rights and entitlements in this Member State related to receiving cross-border healthcare, in particular as regards procedures for accessing and determining those entitlements, conditions for reimbursement of costs and systems of appeal and redress if the patient considers that his/her rights have not been respected.
3. The Member State of affiliation shall ensure that patients that seek to receive or receives cross-border healthcare have access to at least a copy of their medical records, in conformity with and subject to national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.

Article 7

National contact points for cross-border healthcare

1. Each Member State shall designate one or more national contact points for cross-border healthcare and communicate their names and contact details to the Commission.
2. National contact points shall cooperate with each other and with the Commission. National contact point(s) shall provide patients on request with contact details of national contact point(s) in other Member States.
3. National contact point(s) in the Member State of treatment shall provide patients with information concerning healthcare providers, including on request information on a specific providers' right to provide services or any restrictions on its practice, information according to Article 5(2)(a), as well as information on patients' rights, procedures for complaints and for seeking remedies, according to legislation of the Member State.

4. National contact point(s) in the Member State of affiliation shall provide patients with information referred to in Article 6(2).
5. The information shall be easily accessible, including by electronic means.

CHAPTER III

REIMBURSEMENT OF COSTS OF CROSS-BORDER HEALTHCARE

Article 8

General principles for reimbursement of costs

1. Subject to the provisions of Articles 9 and 10, the Member State of affiliation shall ensure reimbursement of costs incurred by an insured person who received cross-border healthcare, if the healthcare in question is among the benefits to which the insured person is entitled in the Member State of affiliation.
 - 1a. By way of derogation from Article 8(1):
 - a) if a Member State is listed in Annex IV of Regulation (EC) No 883/2004 and in compliance with Regulation (EC) No 883/2004 has recognised the rights to sickness benefits for pensioners and the members of their families, being residents in a different Member State, it will provide them healthcare under this Directive at its own expense when they stay on its territory, in accordance with the provisions of the legislation it applies, as though the persons concerned are residents in this Member State listed in Annex IV of Regulation (EC) No 883/2004;

- b) if the healthcare provided in accordance with this directive is not subject to prior authorization, is not provided in accordance with Title III, Chapter 1 of the Regulation (EC) No 883/2004, and is provided in the territory of the Member State that according to Regulation (EC) No 883/2004 and its implementing Regulation is, in the end, responsible for reimbursement of the costs, under those Regulations, it shall be assumed by this Member State. This Member State may assume this healthcare in accordance with the terms, conditions, criteria of eligibility and regulatory and administrative formalities that it has established, provided that this is compatible with the Treaty.
2. It is for the Member State of affiliation to determine, whether at a local, regional or national level healthcare for which an insured person is entitled to assumption of costs and the level of assumption of those costs, regardless of where it is provided.
 3. The costs of cross-border healthcare shall be reimbursed by the Member State of affiliation up to the level of costs that would have been assumed by the Member State of affiliation, had this healthcare been provided in its territory without exceeding the actual costs of healthcare received.
 - 3.a Member States may adopt provisions in accordance with the Treaty aimed at ensuring that patients enjoy the same rights when receiving cross-border healthcare as they would have enjoyed if they had received healthcare in a comparable situation in the Member State of affiliation.
 4. For the purposes of the provisions of paragraph 3, Member States shall have a mechanism for calculation of costs of cross-border healthcare that are to be reimbursed to the insured person by the Member State of affiliation. This mechanism shall be based on objective, non-discriminatory criteria known in advance. The mechanism shall be applied at the relevant administrative level in cases where the Member State of affiliation has a decentralised healthcare system.

5. The Member State of affiliation may impose on an insured person seeking reimbursement of costs of cross-border healthcare, including healthcare received through means of telemedicine, the same conditions, criteria of eligibility and regulatory and administrative formalities, whether set at a local, regional or national level, as it would impose if this healthcare was provided in its territory. This may include an assessment by a health professional or healthcare administrator providing services for the statutory social security system or national health system of the Member State of affiliation, such as the general practitioner or primary care practitioner with whom the patient is registered, if this is necessary for determining the individual patient's entitlement to healthcare. However, no conditions, criteria of eligibility and regulatory and administrative formalities imposed according to this paragraph may be discriminatory or constitute an unjustified obstacle to the free movement of persons, services or goods.
6. The Member State of affiliation shall not make the reimbursement of costs of cross-border healthcare subject to prior authorisation with the exception of Article 9.
7. The Member State of affiliation may limit the application of the rules on reimbursement for cross-border healthcare according to this Article:
 - a) based on overriding reasons of general interest such as the risk of seriously undermining the financial balance of a social security system, or the objective of maintaining a balanced hospital service open to all, and
 - b) to providers that are affiliated to a system of professional liability insurance or a similar arrangement as established by the Member State of treatment according to Article 5(2)(d).
8. The decision to limit the application of Article 8 according to paragraph 7(a) and (b) shall be restricted to what is necessary and proportionate and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of persons, services or goods. Member States shall notify the Commission of any decisions to limit reimbursement on the grounds stated in paragraph 7(a).

Article 9

Healthcare that may be subject to prior authorisation

1. The Member State of affiliation may make the reimbursement of costs of cross-border healthcare subject to prior authorisation, in accordance with the provisions of this Article and Article 10.
2. Healthcare that may be subject to prior authorisation shall be limited to healthcare which:
 - (a) is made subject to planning in so far as it involves overnight hospital accommodation of the patient in question for at least one night or
 - (b) is made subject to planning in so far as it requires use of highly specialised and cost-intensive medical infrastructure or medical equipment or
 - © involves treatments presenting a particular risk for the patient or the population or which could raise serious and concrete concerns related with the quality or safety of the care with the exception of healthcare which is subject to Union legislation ensuring a minimum level of safety and quality throughout the Union;
3. The system of prior authorization, including the criteria for refusing prior authorization to patients, shall be limited to what is necessary and proportionate and shall not constitute a means of arbitrary discrimination.
- 3a. When a patient applies for prior authorisation, the Member State of affiliation shall check whether the conditions of Regulation (EC) No 883/2004 are met. If that is the case, the prior authorisation shall be granted pursuant to that Regulation unless otherwise requested by the patient.

4. The Member State of affiliation may refuse to grant a prior authorisation for reasons including, but not limited to the following:
- (a) the patient is not entitled to the treatment in question, in accordance with Article 8 of this Directive;
 - (b) if this healthcare can be provided on its territory within a time-limit which is medically justifiable, taking into account the current state of health and the probable course of the illness of the person concerned;
 - © if the patient according to a clinical evaluation with reasonable certainty will be exposed to a patient safety risk that cannot be considered to be normal, taking into account the potential benefit for the patient of the sought cross-border healthcare;
 - (d) if the general public with reasonable certainty will be exposed to a substantial safety hazard as a result of the cross-border healthcare in question;
 - (e) if this healthcare is provided by healthcare providers that raise serious and concrete concerns related to the respect of standards and guidelines on quality of care and patient safety, including provisions on supervision, whether these standards and guidelines are given by laws and regulations or through accreditation systems established by the Member State of Treatment.
5. The Member State of affiliation shall make publicly available which healthcare is subject to prior authorisation for the purposes of this Directive as well as all relevant information on the system of prior authorisation.

Article 10

Procedures regarding cross-border healthcare

1. The Member State of affiliation shall ensure that administrative procedures regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State are based on objective, non-discriminatory criteria which are made publicly available in advance, and which are necessary and proportionate to the objective to be achieved.
2. Any such procedural systems shall be easily accessible and capable of ensuring that requests are dealt with objectively and impartially within reasonable time limits set out and made public in advance by the Member States. Urgency and individual circumstances shall be taken into account when dealing with such requests.
3. Member States shall ensure that administrative decisions regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State are subject to administrative review and also capable of being challenged in judicial proceedings, which include provision for interim measures.

CHAPTER IV

COOPERATION ON HEALTHCARE

Article 11

Mutual assistance and cooperation

1. Member States shall render such mutual assistance as is necessary for the implementation of this Directive, including the exchange of information about standards and guidelines on quality and safety, including provisions on supervision, in order to facilitate the implementation of Article 8.7, and including mutual assistance to clarify the content of invoices.
2. Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level.

Article 12

Recognition of prescriptions issued in another Member State

1. If a medicinal product is authorised to be marketed on their territory, Member States shall ensure that prescriptions issued for such a product in another Member State for a named patient can be dispensed in their territory in compliance with their national legislation in force and that any restrictions on recognition of individual prescriptions are prohibited unless they:
 - (a) are limited to what is necessary and proportionate to safeguard human health and are non-discriminatory, or
 - (b) are based on legitimate and justified doubts about the authenticity, content or comprehensibility of an individual prescription.

The recognition of prescriptions shall not affect national rules governing dispensing, if they are compatible with Union law, and shall not affect rules governing generic or other substitution. The recognition of prescriptions shall not affect the rules on reimbursement of medicinal products. Reimbursement of medicinal products is covered by Chapter III of this Directive.

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) no later than 18 months after the publication of this Directive in the Official Journal of the European Union; 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;
 - (b) guidelines supporting the Member States in developing the interoperability of ePrescriptions;
 - © no later than 18 months after the publication of this Directive in the Official Journal of the European Union; measures to facilitate that medicinal products or medical devices prescribed in one Member State and dispensed in another are correctly identified, including measures to address patient safety concerns in relation to the substitution in cross-border healthcare where the legislation of the dispensing Member State permits such substitution. These measures should consider, inter alia, the use of International Non-proprietary Name and the dosage of medicinal products;
 - (d) no later than 18 months after the publication of this Directive in the Official Journal of the European Union, measures to facilitate that the information to patients concerning the prescription and the instructions included on the use of the product is comprehensible;

3. The measures and guidelines referred to in points (a), (b), (c) and (d) of paragraph 2 shall be adopted in accordance with the regulatory procedure referred to in Article 16(2).
4. In adopting measures under paragraph 2 and 3, the Commission shall have regard to the proportionality of any costs of compliance as well as the likely benefits of the measure.
5. For the purpose of paragraph 1, the Commission shall also adopt, by means of delegated acts in accordance with Article 16a and subject to the conditions of Articles 16b and 16c and no later than 18 months after the publication of this Directive in the *Official Journal of the European Union* 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 as provided for in Article 71(2) of Directive 2001/83/EC.

Article 13

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. The networks shall be based on voluntary participation by its members, which shall participate and contribute to the networks activities according to the legislation of the Member State where they are established.
2. The aim of European reference networks shall be to help:
 - (a) realise the potential of European cooperation regarding highly specialised healthcare for patients and for healthcare systems from innovations in medical science and health technologies;
 - (b) facilitate improvements in diagnosis and the delivery of high quality and cost-effective healthcare for all patients with a medical condition requiring a particular concentration of expertise;

- © maximise cost-effective use of resources;
 - (d) reinforce research, epidemiological surveillance like registries and provide training for health professionals;
 - (e) facilitate mobility of expertise, virtually or physically and to develop, share and spread information, knowledge and best practice within and outside the networks;
 - (f) Member States with an insufficient number of patients with a particular medical condition or lacking technology or expertise to provide highly specialised services.
3. Member States are encouraged to facilitate the development of the European reference networks:
- (a) by identifying 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) develop and publish criteria and conditions that the European reference networks should fulfil in order to receive support from the Commission;
 - (b) develop and publish criteria for evaluating European reference networks;
 - © facilitate the exchange of information and expertise in relation to the establishment of networks and their evaluation.
5. The criteria and conditions referred to in paragraph 4 (a), (b) and (c) shall be adopted in accordance with the procedure referred to in Article 16(2).
6. Measures adopted according to this Article shall not harmonize 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 14

eHealth

1. The Commission shall support the Member States towards delivering sustainable economic and social benefits of European e-health systems and services and interoperable applications, with the view to achieve a high level of trust and security, enhance continuity of care and ensure access to safe and quality healthcare.
2. For the purpose of paragraph 1 and in due respect of data protection, the Commission shall elaborate guidelines in close collaboration with the Member States on:
 - (a) a non-exhaustive list of data 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,
 - (b) effective methods for enabling use of medical information for public health and research.
3. For the purpose of paragraph 1 and in due respect to the principles of data protection as set out in particular in Directives 95/46/EC and 2002/58/EC, the Commission shall support the Member States in developing common identification and authentication measures to ensure transferability of data in cross-border healthcare.

Article 15

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 members of the network shall participate and contribute to the network's activities according to the legislation of the Member State where they are established.

2. The objective of the Union support referred to in paragraph 1 shall be:
 - (a) to support Member States in their cooperation through the national authorities or bodies referred to in paragraph 1;
 - (b) and to support Member States in the provision of objective, reliable, timely, transparent and transferable scientific information on the short- and long-term effectiveness of health technologies and enable an effective exchange of this information between the national authorities or bodies.
3. In order to implement paragraph 2, the network on health technology assessment may receive Union aid. Aid may be given 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;
 - © 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. Arrangements for granting the aid, the conditions to which it may be subject and its amount, shall be adopted in accordance with the 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.
5. The appropriations required for measures provided for in this Article shall be decided each year as part of the budgetary procedure.
6. Measures adopted according to this Article shall not interfere with Member States' competence in deciding on the implementation of health technology assessment conclusions and shall not harmonize 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.

CHAPTER V

IMPLEMENTING AND FINAL PROVISIONS

Article 16

Committee

1. The Commission shall be assisted by a Committee, consisting of representatives of the Member States and chaired by the Commission representative.
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 of that Decision. The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 3 months.

Article 16a

Exercise of the delegation

1. The powers to adopt delegated acts referred to in Article 12(5), 14(3) (a) and (b) shall be conferred on the Commission for a period of 5 years beginning on ...^{*}. The Commission shall make a report in respect of the delegated powers not later than 6 months before the end of the 5- year period. The delegation of powers shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 16b.
2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
3. The powers to adopt delegated acts are conferred on the Commission subject to the conditions laid down in Articles 16b and 16c.

^{*} OJ: please insert the date of entry into force of this Directive.

Article 16b

Revocation of the delegation

1. The delegation of power referred to in Article 12(5), 14(3) (a) and (b) may be revoked by the European Parliament or by the Council.
2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of power shall inform the other legislator and the Commission at the latest one month before the final decision is taken, stating the delegated powers which could be subject to revocation and the reasons for a revocation.
3. The decision of revocation shall put an end to the delegation of the powers specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the *Official Journal of the European Union*.

Article 16c

Objections to the delegation

1. The European Parliament and the Council may object to the delegated act within a period of two months from the date of notification.

At the initiative of the European Parliament or the Council this period shall be extended by two months.

2. If, on expiry of that period, neither the European Parliament nor the Council has objected to the delegated act, it shall be published in the *Official Journal of the European Union* and shall enter into force on the date stated therein.

The delegated act may be published in the *Official Journal of the European Union* and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.

3. If the European Parliament or the Council objects to a delegated act, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

Article 17

Reports

1. The Commission shall within five years after the date referred to in Article 19, and subsequently every three years, draw up a report on the operation of this Directive and submit it to the European Parliament and to the Council.
2. The report shall in particular include information on patients' flows, financial dimensions of patients' mobility, the implementation of Article 8(7) and on the functioning of the European reference networks and national contact points. To this end, the Commission shall conduct assessment of the systems and practices put in place in the Member States, in the light of the requirements of this Directive and the other Union legislation relating to patients' mobility.

The Member States shall provide the Commission assistance and available information for carrying out the assessment and preparing the reports.

3. Member States and the Commission shall have recourse to the Administrative Commission established under Article 71 of Regulation (EC) No 883/2004, in order to address the financial consequences on the Member States which have opted for reimbursement on the basis of fixed amounts of the application of the present directive, in cases covered by Articles 20(4) and 27(5) of the same Regulation.

The Commission shall monitor and regularly report on the effect of article 4©1, in this Directive. A first report shall be presented within two years after the entry into force of this Directive. On the basis of these reports, the Commission shall, where appropriate, make proposals to alleviate any disproportionalities.

Article 18

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by ... [three years after its entry into force].
2. They shall forthwith communicate to the Commission the text of those provisions.
3. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 19

Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 20

Addressees

This Directive is addressed to the Member States.

Done at Brussels, [...]

For the European Parliament

For the Council

The President

The President

[...]