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## III

*(Preparatory acts)*

## COUNCIL

**POSITION (EU) No 14/2010 OF THE COUNCIL AT FIRST READING****with a view to the adoption of a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare****Adopted by the Council on 13 September 2010**

(2010/C 275 E/01)

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 European Commission,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,

Having regard to the opinion of the Committee of the Regions <sup>(2)</sup>,

Acting in accordance with the ordinary legislative procedure <sup>(3)</sup>,

Whereas:

(1) According to Article 168(1) of the Treaty, a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities. This implies that a high level of human health protection is to be ensured also when the Union adopts acts under other Treaty provisions.

(2) Article 114 of the Treaty is the appropriate legal basis since the majority of the provisions of this Directive aim

to improve the functioning of the internal market and the free movement of goods, persons and services. Given that the conditions for recourse to Article 114 of the Treaty as a legal basis are fulfilled, Union legislation has to 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 is to 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 the Union'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.

(4) 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 <sup>(4)</sup> (hereinafter the 'Council Conclusions') there is a set of operating principles that are shared by health systems throughout the Union. In the same statement, the Council recognised 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.

(5) As confirmed by the Court of Justice of the European Union (hereinafter the 'Court of Justice') on several occasions, while recognising their specific nature, all types of medical care fall within the scope of the Treaty.

<sup>(1)</sup> OJ C 175, 28.7.2009, p. 116.

<sup>(2)</sup> OJ C 120, 28.5.2009, p. 65.

<sup>(3)</sup> Position of the European Parliament of 23 April 2009 (OJ C 184 E, 8.7.2010, p. 368), Position of the Council of 13 September 2010, Position of the European Parliament of ... (not yet published in the Official Journal) and Decision of the Council of ... .

<sup>(4)</sup> OJ C 146, 22.6.2006, p. 1.

- (6) Some issues relating 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 already been addressed by the Court of Justice. As healthcare is 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 <sup>(1)</sup> it is important to address those 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.
- (7) In the Council Conclusions, the Council recognised the particular value of an initiative on cross-border healthcare ensuring clarity for Union citizens about their rights and entitlements when they move from one Member State to another, in order to ensure legal certainty.
- (8) This Directive aims to establish rules for facilitating access to safe and high-quality cross-border healthcare in the Union and to ensure patient 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 relating to health and for the organisation and delivery of healthcare and medical care and social security benefits, in particular for sickness.
- (9) This Directive should apply 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 the 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 relating to public health. The Member State of affiliation may also take further measures 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.
- (10) 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 of Justice 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 of general interest capable of justifying an obstacle to the freedom to provide services. The Court of Justice 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 of Justice has also held that such 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.
- (11) It is clear that the obligation to reimburse costs of cross-border healthcare should be limited to healthcare to which the insured person is entitled according to the legislation of the Member State of affiliation.
- (12) This Directive should not apply to services the primary purpose of which is to support people in need of assistance in carrying out routine, everyday tasks. More specifically, this Directive should not apply 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 a life as possible. Thus, this Directive should not apply, for example, to long-term care services provided by home care services, in assisted living facilities and in residential homes or housing ('nursing homes').
- (13) Given their specificity, access to and the allocation of organs for the purpose of organ transplants should fall outside the scope of this Directive.
- (14) For the purpose of reimbursing the costs of cross-border healthcare, this Directive should cover not only the situation where the patient is provided with healthcare in a Member State other than the Member State of affiliation, but also the prescription, dispensation and provision of medicinal products and medical devices where these are provided in the context of a health service. The definition of cross-border healthcare should cover both the situation in which a patient purchases such medicinal products and medical devices in a

<sup>(1)</sup> OJ L 376, 27.12.2006, p. 36.

Member State other than the Member State of affiliation and the situation in which the patient purchases such medicinal products and medical devices in another Member State than that in which the prescription was issued.

(15) This Directive should not affect Member States' rules concerning the sale of medicinal products and medical devices over the internet.

(16) This Directive should not give any person an entitlement to enter, stay or reside in a Member State in order to receive healthcare in that State. Where 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 should not be regarded as an insured person according to the definition in this Directive. Member States should continue to be able to specify 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 set out in this Directive are secured.

(17) When a patient receives cross-border healthcare, it is essential for the patient to know in advance which rules will be applicable. The rules applicable to healthcare should be those set out in the legislation of the Member State of treatment, given that, in accordance with Article 168(7) of the Treaty, the organisation and delivery of health services and medical care is the responsibility of the Member States. This should help the patient in making an informed choice, and should avoid misapprehension and misunderstanding. It should also establish a high level of trust between the patient and the healthcare provider.

(18) 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 should 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 are subject to these standards. Furthermore, healthcare providers should provide patients on request with information on specific 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 those specific aspects, this Directive should not oblige healthcare providers to provide more extensive information to patients from other Member States. Nothing should prevent the Member State of treatment from also obliging other actors than the healthcare

providers, such as insurance providers or public authorities, to provide the information on specific aspects of the healthcare services offered, if that would be more appropriate with regard to the organisation of its healthcare system.

(19) Member States should ensure that all patients are treated equitably on the basis of their healthcare needs rather than on the basis of 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 should oblige healthcare providers to accept for planned treatment patients from other Member States or to prioritise them to the detriment of other patients, for instance by increasing the waiting time for treatment of other patients. Inflows of patients may create a demand exceeding the capacities existing in a Member State for a given treatment. 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 should be without prejudice to 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<sup>(1)</sup>.

(20) Systematic and continuous efforts should be made to ensure that quality and safety standards are improved in line with the Council Conclusions and taking into account advances in international medical science and generally recognised good medical practices.

(21) Ensuring clear common obligations in respect of the provision of mechanisms for responding to harm arising from healthcare is essential to prevent lack of confidence in those mechanisms being 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 for the patient.

(22) 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 should be for the Member State to determine the nature and modalities of such a mechanism.

<sup>(1)</sup> OJ L 166, 30.4.2004, p. 1.

- (23) 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 patients' health. These personal data should be able to flow freely from one Member State to another, but at 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<sup>(1)</sup> establishes the right for individuals to have access to their personal data concerning their health, for example the data in their medical records containing such information as diagnosis, examination results, assessments by treating physicians and any treatment or interventions provided. Those provisions should also apply in the context of cross-border healthcare covered by this Directive.
- (24) The right to reimbursement of the costs of healthcare provided in another Member State by the statutory social security system of patients as insured persons has been 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 include 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 should apply to recipients of healthcare seeking to receive healthcare provided in another Member State through other means, for example through e-health services.
- (25) 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.
- (26) This Directive should not affect an insured person's rights in respect of the assumption of costs of healthcare which becomes necessary on medical grounds during a temporary stay in another Member State according to Regulation (EC) No 883/2004. In addition, this Directive should not affect an insured person's right to be granted an authorisation for treatment in another Member State where the conditions provided for by Union regulations on the coordination of social security systems, in particular by Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community<sup>(2)</sup>, 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<sup>(3)</sup>, and Regulation (EC) No 883/2004, are met.
- (27) It is appropriate to require that also patients who seek healthcare in another Member State in other circumstances than those provided for in Regulation (EC) No 883/2004 should be able to benefit from the principles of free movement of services in accordance with the Treaty and with this Directive. Patients should enjoy a guarantee of assumption of the costs of that healthcare at least at the level as would be provided for the same healthcare, had it been provided in the Member State of affiliation. This should fully respect the responsibility of the Member States to determine the extent of the sickness cover available to their citizens and prevent any significant effect on the financing of the national healthcare systems.
- (28) For patients, therefore, the two systems should be coherent; either this Directive applies or the Union regulations on the coordination of social security systems apply.
- (29) Patients should not be deprived of the more beneficial rights guaranteed by the Union Regulations on the coordination of social security systems when the conditions are met. Therefore, any patient who requests an authorisation to receive treatment appropriate to his condition in another Member State should always be granted this authorisation under the conditions provided for in the Unions 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 a time limit that is medically justifiable, taking account of his current state of health and the probable course of the condition. However, if a patient instead explicitly requests to seek treatment under the terms of this Directive, the benefits which apply to reimbursement should be limited to those which apply under this Directive.
- (30) Patients 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 the actual costs of healthcare received.

<sup>(1)</sup> OJ L 281, 23.11.1995, p. 31.

<sup>(2)</sup> OJ L 149, 5.7.1971, p. 2.

<sup>(3)</sup> OJ L 124, 20.5.2003, p. 1.

(31) This Directive does not aim to create an entitlement to reimbursement of the costs 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 should not prevent the Member States from extending their benefits-in-kind scheme to healthcare provided in another Member State. This Directive should recognise that Member States are free to organise their healthcare and social security systems in such a way as to determine entitlement for treatment at a regional or local level.

(32) This Directive should not provide either for the transfer of social security entitlements between Member States or other coordination of social security systems. The sole objective of the provisions regarding prior authorisation and reimbursement of healthcare provided in another Member State should be 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 this Directive should fully respect the differences in national healthcare systems and the Member States' responsibilities for the organisation and delivery of health services and medical care.

(33) This Directive should provide 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 should oblige a Member State of affiliation to reimburse an insured person for a medicinal product prescribed in the Member State of treatment, where that medicinal product 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.

(34) 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, not discretionary or 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, criteria and formalities should be applied in an objective, transparent and non-discriminatory way and should be known in advance, based primarily on medical considerations, and that they should 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 should be made as quickly as possible.

This should be without prejudice to the rights of the Member States to lay down criteria or conditions for 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 goods, persons and services. However, the Member State of treatment may impose conditions, criteria and formalities relating to clinical circumstances, such as assessing the patient-safety risks involved in performing a specific procedure on a specific patient. Furthermore, these conditions, criteria and formalities may 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, so long as such a procedure is neither discriminatory nor an obstacle to the free movement of goods, persons or services.

(35) 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 the free movement of services. Therefore, as a general rule, the Member State of affiliation should not make the assumption of the costs of 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 borne by its statutory social security system or national health system.

- (36) 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 of Justice 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 equipped, 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 of Justice has found that 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. In addition, 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 of Justice, 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 made available for healthcare are not unlimited, whatever mode of funding is applied.
- (37) 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 the Member States regarding the roles of hospitals in their healthcare systems, the question of 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.
- (38) Given that the Member States are responsible for laying down rules as regards the management, requirements, quality and safety standards and organisation and delivery of healthcare and that the planning necessities differ from one Member State to another, it should therefore be for the Member States to decide whether there is a need to introduce a 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 healthcare should be made publicly available.
- (39) The criteria attached to the grant of prior authorisation should be justified in the light of the overriding reasons of 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 and 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 into consideration the general principle of ensuring the safety of the patient, in a sector well known for information asymmetry, when managing a prior authorisation 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 is in and/or the nature of his disability at the time when the request for authorisation was made or renewed.
- (40) According to the constant case law of the Court of Justice, the criteria for granting or refusing prior authorisation should 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 healthcare budget. It should therefore be for Member States to set 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. Consequently, 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.
- (41) In any event, if a Member State decides 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 Regulation (EEC) No 1408/71 or 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 should apply 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 event, Articles 7 and 8 of this Directive should not apply. This is in line with the case law of the Court of Justice which has specified that patients who were refused prior authorisation on grounds that were 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.
- (42) 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 should also apply to the actual reimbursement of costs of healthcare incurred in another Member State after the patient has received treatment.
- (43) 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 has to be provided compulsorily to patients should be specified. However, the national contact points may provide more information voluntarily and also with the support of the Commission. Information should be provided 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 in any other language.
- (44) The Member States should decide on the form and number of their national contact points. Such 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.
- (45) 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 cross-border healthcare. 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 population, 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 (hereinafter 'ICT') 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 7 September 2005 on the recognition of professional qualifications<sup>(1)</sup> stipulates that free provision of services of a temporary or occasional nature, including services provided by health professionals, in another Member State is not, subject to specific provisions of Union law, to be restricted for any reason relating to professional qualifications. This Directive should be without prejudice to Directive 2005/36/EC.
- (46) The Commission should encourage cooperation between Member States in the areas set out in Chapter IV of this Directive and may, in accordance with Article 168(2) of the Treaty, take, in close contact with the Member States, any useful initiative to facilitate and promote such cooperation.
- (47) Where medicinal products are authorised within a Member State and have been prescribed in a Member State by a member of a regulated health profession within the meaning of Directive 2005/36/EC for an individual named patient, it should, in principle, be possible for such prescriptions to be medically recognised and for the medicinal products to be dispensed in another Member State in which the medicinal products are authorised. The removal of regulatory and administrative barriers to such recognition should be without prejudice to the need for appropriate agreement of the patient's 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 should not affect any professional or ethical duty that would require pharmacists to refuse to

<sup>(1)</sup> OJ L 255, 30.9.2005, p. 22.

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 among 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 should 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 should include the adoption of a non-exhaustive list of elements to be included in prescriptions. Nothing should prevent 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.

(48) 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. This Directive should therefore give incentives to Member States to facilitate the continued development of European reference networks. European reference networks are based on the voluntary participation of their members, but the Commission should develop criteria and conditions that the networks should be required to fulfil in order to receive support from the Commission.

(49) Technological developments in cross-border provision of healthcare through the use of ICTs may result in the exercise of supervisory responsibilities by Member States being unclear, and can thus hinder the free movement of healthcare and give rise to possible additional risks to health protection. Widely different and incompatible formats and standards are used for provision of healthcare using ICTs 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. The deployment of health ICT systems, however, is entirely a national

competence. This Directive therefore should recognise the importance of the work on interoperability and respect the division of competences by providing for the Commission and Member States to work together on developing measures which are not legally binding but provide additional tools that are available to Member States to facilitate greater interoperability.

(50) 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 avoid 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. This Directive should therefore provide a basis for continued Union support for such cooperation.

(51) 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 are to 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<sup>(1)</sup> continues to apply, with the exception of the regulatory procedure with scrutiny, which is not applicable.

(52) 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.

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

<sup>(1)</sup> OJ L 184, 17.7.1999, p. 23.

- (54) 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.
- (55) The European Data Protection Supervisor has also delivered his opinion on the proposal for this Directive <sup>(1)</sup>.
- (56) Since the objective of this Directive, namely providing rules for facilitating the access to safe and high quality cross-border healthcare in the Union, cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, 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 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 that objective,

HAVE ADOPTED THIS DIRECTIVE:

#### CHAPTER I

#### GENERAL PROVISIONS

##### Article 1

##### Subject matter and scope

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

<sup>(1)</sup> OJ C 128, 6.6.2009, p. 20.

- (c) with the exception of Chapter IV, public vaccination programmes against infectious diseases which are 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.

4. 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 obliges a Member State to reimburse costs of healthcare provided by healthcare providers established on its own territory if those providers are not part of the social security system or public health system of that Member State.

#### Article 2

##### Relationship with other Union provisions

This Directive shall apply without prejudice to:

- (a) 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 <sup>(2)</sup>;
- (b) 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 <sup>(3)</sup>, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices <sup>(4)</sup> and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices <sup>(5)</sup>;
- (c) Directive 95/46/EC 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 <sup>(6)</sup>;
- (d) 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 <sup>(7)</sup>;
- (e) 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 <sup>(8)</sup>;

<sup>(2)</sup> OJ L 40, 11.2.1989, p. 8.

<sup>(3)</sup> OJ L 189, 20.7.1990, p. 17.

<sup>(4)</sup> OJ L 169, 12.7.1993, p. 1.

<sup>(5)</sup> OJ L 331, 7.12.1998, p. 1.

<sup>(6)</sup> OJ L 201, 31.7.2002, p. 37.

<sup>(7)</sup> OJ L 18, 21.1.1997, p. 1.

<sup>(8)</sup> OJ L 178, 17.7.2000, p. 1.

- (f) Council Directive 2000/43/EC of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin <sup>(1)</sup>;
- (g) 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 <sup>(2)</sup>;
- (h) 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 <sup>(3)</sup>;
- (i) 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 <sup>(4)</sup>;
- (j) Regulation (EC) No 859/2003;
- (k) 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 <sup>(5)</sup>;
- (l) 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 <sup>(6)</sup>;
- (m) Regulation (EC) No 883/2004 and Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems <sup>(7)</sup>;
- (n) Directive 2005/36/EC;
- (o) Regulation (EC) No 1082/2006 of the European Parliament and of the Council of 5 July 2006 on a European grouping of territorial cooperation (EGTC) <sup>(8)</sup>;
- (p) Regulation (EC) No 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work <sup>(9)</sup>;
- (q) 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) <sup>(10)</sup>, 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) <sup>(11)</sup> and other Union rules on private international law, in particular rules related to court jurisdiction and the applicable law.

### Article 3

#### 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:
- (i) persons, including members of their families and their survivors, who are covered by Article 2 of Regulation (EC) No 883/2004 and who are insured persons within the meaning of Article 1(c) of that Regulation, and
  - (ii) nationals of a third country who are covered by Regulation (EC) No 859/2003, or who satisfy the conditions of the legislation of the Member State of affiliation for entitlement to benefits;
- (c) 'Member State of affiliation' means:
- (i) for persons referred to in point (b)(i), 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 Regulation (EC) No 987/2009,
  - (ii) for persons referred to in point (b)(ii), 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

<sup>(1)</sup> OJ L 180, 19.7.2000, p. 22.

<sup>(2)</sup> OJ L 121, 1.5.2001, p. 34.

<sup>(3)</sup> OJ L 311, 28.11.2001, p. 67.

<sup>(4)</sup> OJ L 33, 8.2.2003, p. 30.

<sup>(5)</sup> OJ L 102, 7.4.2004, p. 48.

<sup>(6)</sup> OJ L 136, 30.4.2004, p. 1.

<sup>(7)</sup> OJ L 284, 30.10.2009, p. 1.

<sup>(8)</sup> OJ L 210, 31.7.2006, p. 19.

<sup>(9)</sup> OJ L 354, 31.12.2008, p. 70.

<sup>(10)</sup> OJ L 177, 4.7.2008, p. 6.

<sup>(11)</sup> OJ L 199, 31.7.2007, p. 40.

according to that 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, a nurse responsible for general care, a dental practitioner, 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 Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC;
- (k) 'prescription' means a prescription for a medicinal product or 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 who is legally entitled to do so in the Member State in which the prescription is issued;
- (l) 'health technology' means a medicinal product, 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 REGARD TO CROSS-BORDER HEALTH CARE

#### Article 4

#### 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 with standards and guidelines on quality and safety laid down by that Member State.
2. The Member State of treatment shall ensure that:
  - (a) patients receive upon request relevant information on the 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 the availability, quality and safety of the healthcare they provide in the Member State of treatment, clear invoices and clear 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;
  - (c) there are complaints procedures and mechanisms 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 that is equivalent or essentially comparable as regards its purpose and which is 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 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 may not constitute a means of arbitrary discrimination.

4. Member States shall ensure that the healthcare providers on their territory apply the same scale of fees for healthcare for patients from other Member States, as for domestic patients in a comparable situation, or that they 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 shall not affect laws and regulations in Member States on the use of languages, nor shall it imply any obligation to deliver information in other languages than those which are official languages in the Member State concerned.

#### Article 5

##### **Responsibilities of the Member State of affiliation**

The Member State of affiliation shall ensure that:

- (a) the cost of cross-border healthcare is reimbursed in accordance with Chapter III;
- (b) there are mechanisms in place to provide patients on request with information on their rights and entitlements in that Member State relating 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 patients considers that their rights have not been respected;

- (c) patients who seek to receive or do receive 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 6

##### **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 points shall provide patients on request with contact details of national contact points in other Member States.

3. National contact points in the Member State of treatment shall provide patients with information concerning healthcare providers, including on request information on a specific provider's right to provide services or any restrictions on its practice, information referred to in Article 4(2)(a), as well as information on patients' rights, complaints procedures and mechanisms for seeking remedies, according to the legislation of that Member State.

4. National contact points in the Member State of affiliation shall provide patients with the information referred to in Article 5(b).

5. The information referred to in this Article shall be easily accessible, including by electronic means.

#### CHAPTER III

##### **REIMBURSEMENT OF COSTS OF CROSS-BORDER HEALTHCARE**

#### Article 7

##### **General principles for reimbursement of costs**

1. Subject to the provisions of Articles 8 and 9, the Member State of affiliation shall ensure the costs incurred by an insured person who receives cross-border healthcare are reimbursed, if the healthcare in question is among the benefits to which the insured person is entitled in the Member State of affiliation.

2. By way of derogation from paragraph 1:

(a) if a Member State is listed in Annex IV to Regulation (EC) No 883/2004 and in compliance with that Regulation has recognised the rights to sickness benefits for pensioners and the members of their families, being resident in a different Member State, it shall provide them healthcare under this Directive at its own expense when they stay on its territory, in accordance with its legislation, as though the persons concerned were residents in the Member State listed in that Annex;

(b) if the healthcare provided in accordance with this Directive is not subject to prior authorisation, is not provided in accordance with Chapter 1 of Title III of the Regulation (EC) No 883/2004, and is provided in the territory of the Member State that according to that Regulation and Regulation (EC) No 987/2009 is, in the end, responsible for reimbursement of the costs, the costs shall be assumed by that Member State. That Member State may assume the costs of the healthcare in accordance with the terms, conditions, criteria for eligibility and regulatory and administrative formalities that it has established, provided that these are compatible with the Treaty.

3. It is for the Member State of affiliation to determine, whether at a local, regional or national level, the healthcare for which an insured person is entitled to assumption of costs and the level of assumption of those costs, regardless of where the healthcare is provided.

4. 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.

5. 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.

6. For the purposes of paragraph 4, 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.

7. The Member State of affiliation may impose on an insured person seeking reimbursement of the 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 were 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 goods, persons or services.

8. The Member State of affiliation shall not make the reimbursement of costs of cross-border healthcare subject to prior authorisation except in the cases set out in Article 8.

9. 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, a guarantee or a similar arrangement as established by the Member State of treatment according to Article 4(2)(d).

10. The decision to limit the application of this Article pursuant to paragraph 9(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 goods, persons or services. Member States shall notify the Commission of any decisions to limit reimbursement on the grounds stated in paragraph 9(a).

#### Article 8

##### 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 this Article and Article 9.

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;
- (b) is made subject to planning in so far as it requires the use of highly specialised and cost-intensive medical infrastructure or medical equipment; or
- (c) involves treatments presenting a particular risk for the patient or the population or which could raise serious and specific concerns relating to 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 authorisation, including the criteria for refusing prior authorisation to patients, shall be limited to what is necessary and proportionate and may not constitute a means of arbitrary discrimination.

4. 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. Where those conditions are met, the prior authorisation shall be granted pursuant to that Regulation unless the patient requests otherwise.

5. The Member State of affiliation may refuse to grant prior authorisation for reasons including, but not limited to, the following:

- (a) if the patient is not entitled to the healthcare in question, in accordance with Article 7;
- (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;
- (c) if the patient will, according to a clinical evaluation, be exposed with reasonable certainty to a patient-safety risk that cannot be regarded as acceptable, taking into account the potential benefit for the patient of the sought cross-border healthcare;
- (d) if the general public will be exposed with reasonable certainty to a substantial safety hazard as a result of the cross-border healthcare in question;

(e) if this healthcare is to be provided by healthcare providers that raise serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety, including provisions on supervision, whether these standards and guidelines are laid down by laws and regulations or through accreditation systems established by the Member State of treatment.

6. 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 9*

#### **Administrative 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 procedure referred to in paragraph 1 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 each Member State. 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 are capable of being challenged in judicial proceedings, which include provision for interim measures.

#### CHAPTER IV

#### **COOPERATION IN HEALTHCARE**

#### *Article 10*

#### **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 7(9), 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 11

##### 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 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 prescriptions shall not affect national rules governing dispensing, if those rules 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 costs 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 ... (\*) 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;
- (c) no later than ... (\*) 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.

tution. The Commission shall consider, *inter alia*, using the International Non-proprietary Name and the dosage of medicinal products;

- (d) no later than ... (\*) measures to facilitate the comprehensibility of the information to patients concerning the prescription, and the instructions included therein, on the use of the medicinal products or medical devices.

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 15(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 16 and subject to the conditions of Articles 17 and 18 and no later than ... (\*) 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

##### 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 the voluntary participation of their members, which shall participate and contribute to the networks' activities in accordance with the legislation of the Member State where the members 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 by exploiting 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;

(\*) 18 months after the entry into force of this Directive.

- (c) 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 that have an insufficient number of patients with a particular medical condition or that lack 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;
- (c) facilitate the exchange of information and expertise in relation to the establishment of European reference networks and the evaluation of them.

5. The criteria and conditions referred to in paragraph 4 shall be adopted in accordance with the regulatory procedure referred to in Article 15(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

#### 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 a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and quality healthcare.

2. For the purpose of paragraph 1 and in due observance of the principles of data protection as set out in particular in Directives 95/46/EC and 2002/58/EC, the Commission shall:

- (a) draw up guidelines in close collaboration with the Member States 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;
- (b) support the Member States in developing common identification and authentication measures to facilitate transferability of data in cross-border healthcare.

### Article 14

#### 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 in, and contribute to, the network's activities in accordance with the legislation of the Member State where they are established.

2. The objectives of the Union support referred to in paragraph 1 shall be to:

- (a) support Member States in their cooperation through the national authorities or bodies referred to in paragraph 1; and

(b) 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 to enable an effective exchange of this information between the national authorities or bodies.

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. 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 15(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 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.

## CHAPTER V

### IMPLEMENTING AND FINAL PROVISIONS

#### Article 15

##### 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 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

#### Article 16

##### Exercise of the delegation

1. The powers to adopt delegated acts referred to in Article 11(5) shall be conferred on the Commission for a period of five years from ... (\*). The Commission shall make a report in respect of the delegated powers not later than six months before the end of the five-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 17.

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 17 and 18.

#### Article 17

##### Revocation of the delegation

1. The delegation of power referred to in Article 11(5) may be revoked at any time 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 endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated powers which could be subject to revocation and possible 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 18

##### Objections to delegated acts

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

(\*) Date of entry into force of this Directive.

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 19

##### Reports

1. The Commission shall by ... (\*) and subsequently every three years thereafter, 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 patient flows, financial dimensions of patient mobility, the implementation of Article 7(9) and on the functioning of the European reference networks and national contact points. To this end, the Commission shall conduct an 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 patient mobility.

The Member States shall provide the Commission with 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 of the application of this Directive on the Member States which have opted for reimbursement on the basis of fixed amounts, in cases covered by Articles 20(4) and 27(5) of that Regulation.

The Commission shall monitor and regularly report on the effect of Article 3(c)(i) of this Directive. A first report shall be presented by ... (\*\*). On the basis of these reports, the Commission shall, where appropriate, make proposals to alleviate any disproportionalities.

#### Article 20

##### Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by ... (\*\*\*). They shall forthwith inform the Commission thereof.

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. The methods of making such reference shall be laid down by the Member States.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

#### Article 21

##### 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 22

##### Addressees

This Directive is addressed to the Member States.

Done at ...

For the European Parliament  
The President

For the Council  
The President

...

...

(\*) 5 years from the date of entry into force of this Directive.

(\*\*) 2 years from the date of entry into force of this Directive.  
(\*\*\*) 3 years from the date of entry into force of this Directive.

## STATEMENT OF THE COUNCIL'S REASONS

### I. INTRODUCTION

On 2 July 2008, the European Commission presented a proposal for a Directive on patients' rights in cross-border healthcare <sup>(1)</sup>. 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).

On 23 April 2009 the EP adopted its first-reading opinion <sup>(2)</sup>, approving 122 amendments to the original Commission proposal. The Economic and Social Committee delivered its opinion on 4 December 2008 <sup>(3)</sup> and the Committee of the Regions on 12 February 2009 <sup>(4)</sup>. The European Data Protection Supervisor (EDPS) delivered his opinion on 2 December 2008 <sup>(5)</sup>.

In accordance with Article 294 of the Treaty, the Council adopted its position at first reading by qualified majority on 13 September 2010.

### II. OBJECTIVE

The objective of the Directive is the establishment of an EU framework for the provision of cross-border healthcare within the EU, which fully respects national competence for organising and delivering healthcare. The original Commission proposal was structured around three main areas:

- **common principles in all EU health systems:** setting out which Member State is responsible for ensuring compliance with the common principles for healthcare, as recognised in the Council conclusions of 1-2 June 2006 on common values and principles in EU health systems <sup>(6)</sup>, and what those responsibilities include, in order to ensure that there is clarity and confidence with regard to which authorities are setting and monitoring healthcare standards;
- **a specific framework for cross-border healthcare:** building on the existing Court of Justice of the EU case law, the Directive should make clear the entitlements of patients to receive healthcare in another Member State, including the limits that Member States can place on its provision as well as the level of financial coverage that would be provided for such healthcare; the financial coverage will be based on the principle that patients can obtain reimbursement up to the amount that would have been paid had they obtained the same treatment at home;
- **EU cooperation on healthcare:** the proposal establishes a framework for EU cooperation in areas such as European reference networks, health technology assessment, e-Health, data collection and quality and safety, in order to enable the potential contribution of such cooperation to be put into practice effectively and sustainably.

### III. ANALYSIS OF THE COUNCIL'S POSITION AT FIRST READING

#### (a) General

The Council adopted in full amendments **23, 34, 39, 40, 41, 44, 46, 47, 54, 56, 58, 61, 84, 95, 96 and 98** and, in large part, amendments **14, 17 and 65**.

The following amendments were accepted in part: **20** (decentralised healthcare and social security systems); **22** (access to medicinal products or medical devices in the Member State of treatment); **30** (deletion of the reference to realising the potential of the internal market for cross-border healthcare); **32** (concerning sales of medicinal products and medical devices over the Internet); **45** (except the prevention part); **48** (except 'medical practitioner'); **51** (except 'private schemes'); **71** (access by patients to their medical records); **97** (information on the existence of national contact points); **101 and 144** (national rules governing dispensing, substitution or reimbursement of medicinal products); and **109** (data protection).

<sup>(1)</sup> 11307/08.

<sup>(2)</sup> 8903/09.

<sup>(3)</sup> SOC/322 – CESE 1927/2008.

<sup>(4)</sup> CdR 348/2008 fin – DEVE-IV-032.

<sup>(5)</sup> 16855/08.

<sup>(6)</sup> OJ C 146, 22.6.2006, p. 1.

The Council included a double legal basis for the Directive (Articles 114 and 168 of the Treaty), which was supported by the Commission.

**(b) Subject matter and scope (Article 1)**

As regards the aim of the Directive, the Council takes the same line as the EP, that the Directive should on the one hand provide for rules to facilitate access to safe, high-quality cross-border healthcare and promote cooperation between the Member States, while on the other hand fully respecting national competence for organising and delivering healthcare, and it adopts amendment 37 in part.

The Council is of the opinion that Article 1(2) covers all the different types of healthcare systems in the Member States and therefore that the wording '*whether it is public or private*' is unnecessary and misleading.

Like the EP, the Council recognised the need to exclude long-term care from the scope of the Directive, thus following the EP (amendments 7 and 38), and limited the exclusion of organ transplantation to access to and allocation of organs (amendments 8 and 38). The Council added the exclusion of public vaccination programmes against infectious diseases.

The definition of '*healthcare*' is consistent with amendments 46 and 96 and covers healthcare that is provided (treatments) or prescribed (medicinal products and/or medical devices) while dropping the reference to professional mobility. The Council also accepted the main part of amendment 9 and deleted the reference to the different modes of supply of healthcare.

**(c) Relationship with Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems <sup>(1)</sup>**

The Council agrees with the EP that the Directive should apply without prejudice to the existing framework on the coordination of social security systems as laid down in Regulation (EC) No 883/2004 (herein after 'the Regulation'). This framework allows the Member States to refer patients abroad for treatment that is not available at home. The Council's position is that when the conditions of the Regulation are met, prior authorisation must be given pursuant to that Regulation, since in the majority of cases this will be more advantageous to the patient. This is consistent with the idea behind, and the relevant parts of, amendments 38, 66, 82, 117 and 128. Nevertheless, the patient can always request to receive healthcare under the Directive.

**(d) Member State of treatment (MST) (Article 4)**

The Council groups together all the responsibilities of the MST in one article. The main responsibilities of the MST are those that the EP asked for in amendments 59 and 140. Furthermore, while recognising the principle of non-discrimination with regard to nationality against patients from other Member States, the Council introduced the possibility for the MST, where justified by overriding reasons of general interest, to adopt measures regarding access to treatment aimed at fulfilling its responsibility to ensure sufficient and permanent access to healthcare within its territory to its insured persons.

The Council followed the thrust of amendment 15 on the necessity for systems to be in place for making complaints, and mechanisms for patients to seek remedies in accordance with the legislation of the MST if they suffer harm arising from the healthcare they have received. In addition, the Council included additional guarantees for patients (e.g. application of the same scale of fees by healthcare providers to cross-border patients).

**(e) Member State of affiliation (MSA) (Article 5)**

As a general principle for reimbursement of the costs of cross-border healthcare, the MSA would have to have a mechanism for calculation of such costs. It can also introduce a system for prior authorisation based on non-discriminatory criteria, limited to what it is necessary and proportionate and applied at the appropriate administrative level. This goes along with what the EP proposed in amendments 63, 70, 79 and 88. These criteria will guarantee insured persons seeking healthcare abroad the same conditions, criteria of eligibility and regulatory and administrative formalities (gate-keeper) as patients staying in the MSA. This approach is in line with amendment 69.

<sup>(1)</sup> OJ L 166, 30.4.2004, p. 1.

According to the Council position, the MSA would have to ensure that there are systems of appeal and redress if the patient considers that his/her rights have not been respected. This covers amendment **81**.

**(f) Prior authorisation (Articles 7(8) and 8)**

The Council agreed to the general principle that reimbursement of the costs of cross-border healthcare must not be subject to prior authorisation in line with amendment **73**. The prior authorisation system that the MSA may introduce pursuant to the Directive, and as an exception to the above-mentioned principle, has to be based on clear and transparent criteria, should avoid unjustified obstacles to the freedom of movement of persons and thus reflects the thrust of amendments **77, 149 and 157**.

The MSA may limit the application of the rules on reimbursement for cross-border healthcare by overriding reasons of general interest or to providers that are affiliated to a system of professional insurance in the MST. In this respect, the Council opted for a different approach than proposed by the EP in amendment **76**.

The basic principles for the procedure for granting the prior authorisation are detailed in the Council's position, and include the obligation to give the reasons for refusal, e.g. the healthcare is provided by providers that raise serious and concrete concerns related to compliance with the applicable quality and safety standards and guidelines. Article 8 of the Council's position refers to the importance of transparency in the operation of the prior authorisation system in line with amendment **25**. The Council has also included urgency and individual circumstances among the aspects to be evaluated when taking administrative decisions on granting the prior authorisation, taking into account the spirit of amendments **87 and 145**.

The Council limited the healthcare that may be subject to prior authorisation to healthcare that the EP defined as '*hospital care*' in its amendment **75** and took the approach of focusing on the factors justifying it (Article 8(2)). The Council agrees with the EP that there should not be a common EU-wide list of healthcare, but that it is for the Member States to define it.

**(g) Pensioners living abroad (Article 7.2)**

When pensioners and members of their families whose MSA is listed in Annex IV to the Regulation reside in a different Member State, this MSA has to provide them with healthcare at its own expense when they stay on its territory.

If the healthcare provided in accordance with the Directive is not subject to prior authorisation, is not provided in accordance with Chapter 1 of Title III of the Regulation, and is provided in the territory of the Member State that, according to the Regulation, is, in the end, responsible for reimbursement of the costs, the costs should be assumed by that Member State.

**(h) Direct payment and the concepts of prior notification and of vouchers**

The Council rejects amendments **78 and 86** as it considers them contrary to the competence of the Member States to organise their health systems, in particular when it comes to the regulation of upfront payments. The Council considers the content of amendment **91** unfeasible in practice as the healthcare that a patient might receive abroad and its cost cannot be known beforehand.

**(i) Equal treatment of patients and extension of entitlements to reimbursement**

The Council has not incorporated amendments **19, 21, 66, 68 and 83** in order to respect the principle of equal treatment for all insured persons from the same MSA regardless of the MST. The explicit reference to particular pieces of legislation on equal treatment (amendments **136, 137 and 138**) is unnecessary as the principle is embodied in the Council's text (Articles 4, 7, 8, 9 and 11). The Council's position states that the Member States have to ensure that all patients are treated equitably on the basis of their healthcare needs, which reflects amendment **13**.

(j) **Goods used in connection with healthcare**

The Council has not included the definition of '*goods used in connection with healthcare*' proposed in amendment **55** and prefers to use the definitions of '*medical device*' and '*medicinal product*' that already exist in EU legislation and would not pose transposition and implementation problems. Therefore, the Council has not incorporated amendments **18, 19 and 20** that make use of these terms.

(k) **Continuity of care**

The Council considered that ensuring continuity of care is an important aspect of the provision of cross-border healthcare and that it should be achieved through practical mechanisms, the transfer of personal data, e-health and sharing of information between health professionals. In agreeing on these aspects (recitals 23 and 45 and Article 13) the Council drew on the relevant parts of amendments **35 and 60**.

(l) **Information for patients and the National Contact Points (NCPs) (Article 6)**

The Member States must provide patients on request with relevant information on the safety and quality of the healthcare provided as well as on their entitlements and rights. This is in line with parts of amendments **11 and 93**.

The NCPs have to cooperate with each other and with the Commission (amendment **99**). In addition, the NCPs have to provide patients with information concerning healthcare providers, and, on request, on any restrictions on their practice. They should also provide information to patients on procedures for complaints and for seeking remedies and on provisions on supervision and assessment of healthcare providers. All this information should be easily accessible, including by electronic means, which reflects the thrust of amendments **27, 29 and 94**.

(m) **Data collection and protection**

The Council's text includes several provisions creating obligations in relation to the protection of personal data on the MST (Article 4(2)(b) and (f)) and MSA (Article 5(c)) and in relation to e-Health (Article 13(3)) reflecting the existing EU legislation on protection of personal data. In this manner amendments **16 and 112** have been taken into account.

(n) **Other**

The Council's position at first reading also includes a number of changes in Chapter V (Implementing and final provisions). The Council did not accept amendments **105, 113 and 143** as the involvement of stakeholders or of the European Data Protection Supervisor in the procedures for the exercise of implementing powers conferred on the Commission is not provided for in Council Decision 1999/468/EC.

Given the entry into force of the TFEU, the Council included new Articles 16, 17 and 18 on the exercise of powers to adopt delegated acts conferred on the Commission, their revocation and objections to them in relation to the exclusion of specific categories of medicinal products or medical devices from the recognition of prescriptions (Article 11(5)).

The Council has completed amendment **115** by including information on patient flows (as the EP requested) and on the financial dimension of patients' mobility in the contents of the reports on the operation of the Directive. The Council has not followed amendment **90** requesting the Commission to conduct a feasibility study into the establishment of a clearing house for the reimbursement of costs.

The Council's position does not reflect a number of amendments because they are deemed unnecessary and/or in conflict with the Council's position. In particular:

- Amendment **1**: Article 114 of the Treaty says that approximation measures proposed by the Commission in the field of health must have as a base a high level of protection;
- Amendment **2**: does not relate to any operational provision of the Directive;
- Amendments **4 and 10**: refer to ethical issues that are not appropriate for regulation at EU level;



- Amendment **5**: healthcare is excluded from the scope of Directive 2006/123/EC (the Services Directive, Article 2(2)(f));
- Amendment **6**: is rejected due to its mainly linguistic nature;
- Amendment **12**: it is not acceptable to suggest that a Member State could try to oblige a patient to receive treatment abroad;
- Amendment **24**: the Council found it unfeasible to compare ‘a priori’ healthcare in terms of its effectiveness for the patient;
- Amendments **28 and 110**: despite the fact that the Council has not included this amendment, telemedicine is among the types of healthcare covered by the Directive and is subject to the same professional and quality and safety requirements as any other healthcare;
- Amendments **31 and 139**: reference to draft legislation is legally undesirable;
- Amendments **33 and 135**: health technology assessments have to be performed in an independent manner and protected from stakeholder involvement;
- Amendment **36**: it is not for the Directive to put forward a hypothesis about its effects on competition between service providers;
- Amendment **42**: was not accepted as the possible relationship of the Directive with the Union legislation quoted in the amendment was not clear;
- Amendment **49**: was not followed by the Council, which preferred a broader definition of ‘*healthcare provider*’ in order to cover all types present in the Member States;
- Amendments **52 and 53**: the Council opted for a more comprehensive definition of ‘*Member State of affiliation*’ based on existing Union legislation;
- Amendment **57**: the definition of ‘*harm*’ was not included as it only refers back to the definition of harm fixed by national legislation and is therefore unnecessary;
- Amendments **62 and 64**: were not accepted as there is no need to have Commission guidelines or third party involvement in the responsibilities of the MST in cases of cross-border healthcare;
- Amendment **72**: its justification was not understood and its inclusion rejected;
- Amendment **74**: the Council opted for a general term, ‘healthcare’, that includes hospital and specialised care and also treatments, medicinal products, medical devices, etc.
- Amendment **80**: is unnecessary as Member States have a legal obligation to ensure patients have access to prior authorisation schemes, if they have decided to introduce them;
- Amendment **85**: was rejected as in contradiction with amendment 25;
- Amendment **89**: the Council did not find any justification for this amendment;
- Amendment **92**: the Council did not accept this amendment as how it would relate to existing national arrangements is unclear. It should be noted that the Commission has the right of initiative in proposing EU legislation and cannot be obliged by a legislative act to make a legislative proposal;

- Amendments **102, 103, 104, 106 and 107**: the Council found these amendments too prescriptive and restrictive of the activities of the European reference networks;
- Amendments **100 and 108**: bilateral agreements between Member States exist already in the field of cross-border healthcare and there is no need to include this possibility in the Directive; in addition the Council saw a risk of overlap between the 'trial areas' and existing ongoing projects on healthcare across border regions;
- Amendment **141**: the Council considered the definition of '*health data*' unclear because it mixed information on health status and administrative information.

#### IV. CONCLUSION

The Council believes that its position at first reading represents a fair balance between the rights of patients in cross-border healthcare and the responsibilities of the Member States for the organisation and delivery of health services and medical care.

It looks forward to constructive discussions with the European Parliament at second reading with a view to early adoption of the Directive.

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