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Patients' rights in cross-border healthcare ***I

P6_TA(2009)0286

European Parliament legislative resolution of 23 April 2009 on the proposal for a directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare (COM(2008)0414 – C6-0257/2008 – 2008/0142(COD))

(2010/C 184 E/73)

(Codecision procedure: first reading)

The European Parliament,

— having regard to the Commission proposal to the European Parliament and the Council (COM(2008)0414),

— having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0257/2008),

— having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,

— having regard to Rules 51 and 35 of its Rules of Procedure,

— having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Employment and Social Affairs, the Committee on the Internal Market and Consumer Protection, the Committee on Economic and Monetary Affairs, the Committee on Committee on Industry, Research and Energy, Committee on Legal Affairs and the Committee on Women's Rights and Gender Equality (A6-0233/2009),

1. Approves the Commission proposal as amended;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council and Commission.

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P6_TC1-COD(2008)0142

Position of the European Parliament adopted at first reading on 23 April 2009 with a view to the adoption of Directive *2009/…/EC* of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission ‖,

Having regard to the opinion of the European Economic and Social Committee [1],

Having regard to the opinion of the Committee of the Regions [2],

After consulting the European Data Protection Supervisor [3],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [4],

Whereas:

(1) *In accordance with* Article 152(1) of the Treaty, a high level of human health protection must be ensured in the definition and implementation of all Community policies and activities. This implies that *a* high level of human health protection has to be ensured also when the Community ‖ acts under other Treaty provisions.

(2) Given that the conditions for recourse to Article 95 of the Treaty as a legal basis are fulfilled, the Community ‖ shall rely on this legal basis even when public health protection is a decisive factor in the choices made; in this respect Article 95(3) of the Treaty explicitly requires that ▌a high level of protection of human health should be guaranteed taking account in particular of any new development based on scientific facts.

(3) On 9 June 2005 the European Parliament adopted, by 554 votes to 12, a resolution on patient mobility and healthcare developments in the European Union [5], in which it called for legal certainty and clarity on rights and procedures for patients, health professionals and Member States.

(4) This Directive respects the fundamental rights and observes the general principles of law as recognised in particular by the Charter of Fundamental Rights of the European Union [6] *('the Charter')*. The right of access to healthcare and the right to benefit from medical treatment under conditions established by national law and practices are recognised by Article 35 of the Charter ‖. Specifically, this Directive has to be implemented and applied with due respect for the rights to private and family life, protection of personal data, equality before the law and the principle of non-discrimination and the right to an effective remedy and to a fair trial, in accordance with the general principles of law, as enshrined in Articles 7, 8, 20, 21, 47 of the Charter.

(5) The health systems of the Community are a central component of Europe's high levels of social protection, and contribute to social cohesion and social justice as well as to sustainable development. They are also part of the wider framework of services of general interest.

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[1] *Opinion of 4 December 2008 (not yet published in the Official Journal).*
[2] *OJ C 120, 28.5.2009, p. 65.*
[3] *OJ C 128, 6.6.2009, p. 20.*
[4] *Position of the European Parliament of 23 April 2009.*
[5] ***OJ C 124 E, 25.5.2006, p. 543.***
[6] OJ C 364, 18.12.2000, p. 1.

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(6) This Directive respects and does not prejudice the freedom of each Member State to decide what type of healthcare it considers appropriate. No provision of this Directive should be interpreted in such a way as to undermine the fundamental ethical choices of Member States.

(*7*) As confirmed by the Court of Justice on several occasions, while *recognising* their specific nature, all types of medical care fall within the scope of the Treaty.

(*8*) Some issues related to cross-border healthcare, in particular reimbursement of healthcare provided in a Member State other than that in which the recipient of the care is resident, have been already addressed by the Court of Justice. ▌It is important to address these issues in a specific Community 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.

(*9*) In its Conclusions of 1-2 June 2006 *on Common values and principles in European Union health systems* ([1]) *('Council Conclusions of 1-2 June 2006')*, the Council ‖ adopted a statement on 'Common values and principles' ‖ and recognised *the* particular value of an initiative on cross-border healthcare ensuring clarity for European citizens about their rights and entitlements when they move from one Member State to another in order to ensure legal certainty.

(*10*) This *Directive* aims to establish a general framework for provision of safe, high quality and efficient cross-border healthcare in the Community ***in relation to*** patients mobility ***as well as a to a*** high level of protection of health, whilst fully respecting the responsibilities of the Member States for the definition of social security benefits related to health and ***for*** the organisation and delivery of healthcare and medical care ***as well as of*** social security benefits in particular for sickness.

(*11*) This Directive on the application of patients' rights in cross-border healthcare applies to all types of healthcare. As confirmed by the Court of Justice, neither *the* special nature *of healthcare* nor the way in which *it is* organised or financed removes *it* from the ambit of the fundamental principle of freedom of movement. As regards long-term care, *this* Directive does not apply to assistance and support for families or individuals who are, over an extended period of time, in ‖ particular ‖ need ***of nursing, support or care in so far as this involves specific expert treatment or help provided by a social security system, including above all such long-term care services as are considered necessary in order to provide the person in need of care with as full and independent a life as possible. This Directive*** does not apply, for example, to residential homes or housing, or assistance provided to elderly people or children by social workers or volunteer carers or professionals other than health professionals.

(12) This Directive does not apply to organ transplantations. Due to their specific nature, they will be regulated by a separate directive.

(*13*) For the purpose of this Directive, the concept of 'cross-border healthcare' ***only*** covers the ***use of healthcare in a Member State other than that where the patient is an insured person. This is what is referred to as 'patient mobility'***.

(*14*) As recognised by the Member States in the Council *Conclusions of 1-2 June 2006*, there is a set of operating principles that are shared by health systems throughout the Community. *Those* operating principles include quality, safety, care that is based on evidence and ethics, patient involvement, redress, the fundamental right to privacy with respect to the processing of personal data, and confidentiality. Patients, professionals and authorities responsible for health systems must be able to rely on *those* operating principles being respected and structures provided for their implementation throughout the Community. It is therefore appropriate to require that it is the authorities of the Member State on whose territory the healthcare is provided, *which* are responsible for ensuring compliance with those operating principles. This is necessary to ensure the confidence of patients in cross-border healthcare, which is itself necessary for achieving *patients* mobility ▌as well as a high level of health protection. ***Notwithstanding those common values it is accepted that Member States take different decisions on ethical grounds as regards the availability of certain treatments and the concrete access conditions. This Directive is without prejudice to ethical diversity.***

([1]) OJ C 146, 22.6.2006, p. 1.

(*15*) Given that it is impossible to know in advance whether a given healthcare provider will supply healthcare to a patient coming from another Member State or a patient from their own Member State, it is necessary *for* the requirements to ensure that healthcare is provided *in accordance with* common principles and clear quality and safety standards are applicable to all *types* of healthcare in order to ensure the freedom to provide and obtain crossborder healthcare, which is the aim of the *Directive*. Member States' authorities have to respect the shared overarching values of universality, access to good quality care, equity and solidarity, which have been already widely recognised by the Community institutions and by all the Member States as constituting a set of values that are shared by health systems across Europe. Members States also have to ensure that these values are respected with regard to patients and citizens from other Member States, and that all patients are treated equitably on the basis of their healthcare need rather than their Member State of social security affiliation. In doing so, Member States must respect the principles of freedom of movement ***of individuals*** within the internal market, non-discrimination inter alia with regard to nationality, ▌ necessity and proportionality of any restrictions on free movement. However, nothing in this Directive requires healthcare providers to accept for planned treatment or to prioritise patients from other Member States to the detriment of other patients with similar health needs, such as through increasing waiting time for treatment. ***In order to enable patients to make an informed choice when they seek to receive healthcare in another Member State, Member States should ensure that patients receive on request the relevant information on health and quality standards enforced in the Member State of treatment as well as on the characteristics of healthcare provided by a specific healthcare provider. Such information should also be made available in formats accessible to persons with disabilities.***

(*16*) Moreover, patients from other Member States should enjoy equal treatment with the nationals of the Member State of treatment and, according to the general principles of equity and non discrimination, as *recognised* in Article 21 of the Charter, they should in no way be discriminated *against* on the basis of their sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation. Member States may differentiate in the treatment accorded to different groups of patients only where they can demonstrate that this is justified by legitimate medical grounds, such as in case of specific measures for women or for certain ages groups (e.g. free of charge vaccination for children or elderly people). Furthermore, as this Directive respects the fundamental rights and observes the principles recognised in particular by the Charter ‖, it has to be implemented and applied with due respect for the *right* to equality before the law and the principle of non-discrimination in accordance with the general principles of law, as enshrined in Articles 20 and 21 of the Charter. This Directive applies without prejudice to Council Directive 2000/43/EC of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin [1], ***Council Directive 2004/113/EC of 13 December 2004 implementing the principle of equal treatment between men and women in the access to and supply of goods and services [2], Council Directive 2000/78/EC of 27 November 2000 establishing a general framework for equal treatment in employment and occupation [3], and Council Directive 2009/…/EC of … On implementing the principle of equal treatment between persons irrespective of religion or belief, disability, age or sexual orientation*** [4] ‖ giving effect to Article 13 of the ‖ Treaty. In the light of this, this Directive provides that patients shall enjoy equal treatment with the nationals of the Member State of treatment, including the benefit from the protection against discrimination provided for according to Community law as well as from the legislation of the Member State of treatment.

(17) Member States should ensure that in the application of this Directive patients are not encouraged against their will to receive treatment outside of their Member State of affiliation.

(18) It is also important to put in place measures to ensure that women have equitable access to public health schemes and care that is specific to them, particularly gynaecological and reproductive healthcare.

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[1] *OJ L 180, 19.7.2000, p. 22.*
[2] ***OJ L 373, 21.12.2004, p. 37.***
[3] ***OJ L 303, 2.12.2000, p. 16.***
[4] OJ L …

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(*19*) In any event, any *measures* taken by Member States with a view to *ensuring* that healthcare is provided *in accordance with* clear quality and safety standards, should not constitute new barriers to the free movement of health professionals as enshrined *in* the Treaty and in particular regulated by Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications ([1]).

(20) Systematic and continuous efforts should be made to ensure that quality and safety standards are improved, in line with the Council Conclusions of 1-2 June 2006 ‖ and taking into account advances in international medical science and generally recognised good medical practices as well as taking into account new health technology.

(*21*) Research suggests that harm arises from healthcare in around 10 % of cases. Ensuring ***that Member States of treatment have systems in place (including provision of aftercare)*** to deal with ***alleged*** harm arising from healthcare ***as defined by the Member State of treatment*** is therefore essential to avoid lack of confidence in those mechanisms acting as an obstacle to taking up cross-border healthcare. Coverage for harm and compensation by the systems of 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 *one Member State* seeking healthcare *in another Member State*, where this is more appropriate to the patient, in particular in the case of patients for whom use of healthcare in another Member State is necessary.

(*22*) Member States should ensure ‖ that mechanisms for the protection of patients and ‖ compensation for harm are in place for healthcare provided on their territory and that they are appropriate to the nature and extent of the risk. However, it is for the Member State to determine the nature and/or modalities of such a mechanism.

(*23*) The right to the protection of personal data is a fundamental right recognised by Article 8 of the Charter ‖. Ensuring continuity of cross-border healthcare depends on transfer of personal data concerning patient's health. *Those* 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 ([2]) establishes the right for individuals to have access to their personal data concerning their health, for example in the patient's medical records containing such matters as diagnosis, examination results, assessments by treating physicians and any treatment or interventions provided. These provisions also apply in the context of cross-border healthcare covered by this Directive. ***The patient should be able to stop the release of his data at any point and receive confirmation that his data have been deleted.***

(*24*) The right to reimbursement of the costs of healthcare provided in another Member State from the statutory social security scheme of patients as insured persons *has been* recognised by the Court of Justice in several judgements. The Court of Justice has held that the Treaty provisions ***include*** the freedom ▌for the recipients of healthcare, including persons in need of medical treatment, to go to another Member Sate in order to receive it there. ▌Community law does not detract from the power of the Member States to organise their healthcare and social security systems ▌.

(*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.

([1]) OJ L 255, 30.9.2005, p. 22. ‖
([2]) OJ L 281, 23.11.1995, p. 31.

(*26*) This Directive does not address the assumption of costs of healthcare which become necessary on medical grounds during a temporary stay of insured persons in another Member State. Neither does this Directive affect *patients*' rights to be granted an authorisation for ‖ treatment in another Member State where the conditions provided for by the regulations on coordination of social security schemes, in particular Article 22 of Council Regulation (*EEC*) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community [1] and Article 20 of Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems [2] are met.

(*27*) ▌Patients should be guaranteed assumption of the costs of ▌healthcare ***and goods connected with healthcare provided in a Member State other than their Member State of affiliation*** at least at the level provided for ***treatment which is*** the same or ***equally effective,*** had they been provided ***or purchased*** in the Member State of affiliation. This fully respects *the* responsibility of the Member States to determine the extent of the sickness cover available to their citizens and prevents any significant effect on the financing of the national healthcare systems. Member States may nevertheless provide in their national legislation for reimbursement of the costs of the treatment at the tariffs in force in the Member State of treatment if this is more beneficial for the patient. This may be the case in particular for any treatment provided through European reference networks *referred to* in *Article 17* of this Directive.

(*28*) For the patient, therefore, the two systems are coherent; either this *Directive* applies or Regulation *(EEC) No* 1408/71 *applies*. In any event, any insured person who requests an authorisation to receive a treatment appropriate to his/her condition in another Member State *should* always be granted this authorisation under the conditions provided for in *Regulations (EEC) No* 1408/71 and *(EC) No* 883/*2004* when the treatment in question cannot be given within the time medically justifiable, taking *into* account *the patient's* current state of health and the probable course of the disease. The patient should not be deprived of the more beneficial rights guaranteed by *those Regulations* when the conditions are met.

(*29*) The patient may choose which mechanism they prefer, but in any case, where the application of Regulation *(EEC) No* 1408/71 is more beneficial for the patient, the patient should not be deprived of the rights guaranteed by that Regulation.

(*30*) The patient should, in any event, not derive a financial advantage from the healthcare provided ***or goods purchased*** in another Member State ▌. The assumption of costs should *therefore be* limited only to *the* actual costs. ***Member States may decide to cover other related costs, such as therapeutic treatment, provided that the total cost does not exceed the amount payable in the Member States of affiliation.***

(*31*) This Directive does not aim either to create entitlement for reimbursement of treatment ***or of the cost of purchasing goods*** in another Member State, if such a treatment ***or such goods are*** not among the benefits provided for by the legislation of the patient's Member State of affiliation. Equally this Directive does not prevent the Member States from extending their benefits in kind scheme to healthcare ***and goods*** provided in another Member State according to its provisions. ***This Directive recognises that entitlement to treatment is not always determined nationally by Member States and that Member States may organise their own healthcare and social security systems in such a way as to provide for entitlement to treatment to be determined at a regional or local level.***

(32) If there are several methods available for treating a certain disease or injury, the patient should have the right to reimbursement for all methods of treatment that are sufficiently tried and tested by international medical science, even if they are not available in the patient's Member State of affiliation.

[1] OJ L 149, 5.7.1971, p. 2. ‖
[2] OJ L 166, 30.4.2004, p. 1.

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(33) This Directive does not provide either for transfer of social security entitlements between Member States or other coordination of social security schemes. The sole objective of the provisions regarding prior authorisation and reimbursement of healthcare provided in another Member State is to enable freedom to provide healthcare for both patients and healthcare providers and to remove unjustified obstacles to that fundamental freedom within the patient's Member State of affiliation. Consequently *this* Directive fully respects the differences *between* national *healthcare* systems and the Member States' responsibilities for organisation and delivery of health services and medical care.

(34) This Directive provides also for the right for a patient to receive any medicinal product ***or medical device*** authorised for marketing in the Member State ***of treatment***, even if *that* medicinal product ***or medical device*** is not authorised for marketing in the Member State of affiliation, as it is an indispensable part of obtaining ***this specific*** effective treatment ***for the patient*** in another Member State.

(35) 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, *including* in relation to patients seeking healthcare in another Member State provided that such conditions are necessary, proportionate to the aim and are not discretionary and discriminatory. It is thus appropriate to require that *those* general conditions and formalities are being applied in an objective, transparent and non-discriminatory way and are known in advance, that they are based primarily on medical considerations and that they do not impose any additional burden on patients seeking healthcare in another Member State *compared to* patients being treated in their Member State of affiliation, and that decisions are made as quickly as possible. This is without prejudice to the rights of the Member States to provide for criteria or conditions of prior authorisation in the case of patients seeking healthcare in their Member State of affiliation.

(36) Any healthcare which is not regarded as hospital care *in accordance with* the provisions of this Directive should be considered as non-hospital care. In the light of the case-law of the Court of Justice on the free movement of services, it is appropriate not to set a requirement of prior authorisation for reimbursement by the statutory social security system of a Member State of affiliation for non-hospital care provided in another Member State. In so far as the reimbursement of such care remains within the limits of the cover guaranteed by the sickness insurance scheme of the Member State of affiliation, the absence of a prior authorisation requirement will not undermine the financial equilibrium of social security systems.

(37) There is no definition of what constitutes hospital care throughout the different health systems of the Community, and different interpretations could therefore constitute an obstacle to the freedom for patients to receive healthcare. In order to overcome that obstacle, it is necessary to provide a Community definition of hospital care. Hospital care generally means care requiring the overnight accommodation of the patient. However, it may be *also* appropriate to submit to the same regime of hospital care certain other kinds of healthcare, if that healthcare requires use of highly specialised and cost-intensive medical infrastructure or medical equipment (e.g. high-technology scanners used for diagnosis) or involving treatments presenting a particular risk *to* the patient or the population (e.g. treatment of serious infectious diseases). ▌

(38) The evidence available indicates that the application of free movement principles regarding use of healthcare in another Member State within the limits of the cover guaranteed by the statutory sickness insurance scheme of the Member State of affiliation will not undermine the health systems of the Member States or financial sustainability of their social security systems. However, the Court of Justice has recognised that it cannot be excluded that the possible risk of seriously undermining a social security system's financial balance or the objective of maintaining a balanced medical and hospital service open to all may constitute overriding reasons in the general interest capable of justifying a barrier to the principle of freedom to provide services. The Court of Justice has also recognised that the

number of hospitals, their geographical distribution, the way in which they are organised and the facilities with which they are provided, and even the nature of the medical services which they are able to offer, are all matters for which planning must be possible. This Directive should provide for a system of prior authorisation for assumption of costs for hospital care received in another Member State, where the following conditions are met: had the treatment been provided on its territory, it would have been assumed by its social security system and the consequent outflow of patients due to the implementation of the directive seriously undermines or is likely to seriously undermine the financial balance of the social security system and/or *that* outflow of patients seriously undermines, or is likely to seriously undermine, the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the Member *State concerned*. As the assessment of the precise impact of an expected outflow of patients requires complex assumptions and calculations, *this* Directive allows for a system of prior authorisation if there is sufficient reason to expect that the social security system will be seriously undermined. This should also cover cases of already existing systems of prior authorisation which are in conformity with conditions laid down in Article 8.

(*39*) In any event, if a Member State decided to establish a system of prior authorisation for assumption of costs of hospital or specialised care provided in another Member *State* in accordance with the provision of this Directive, the costs of such care provided in another Member State should also be reimbursed by the Member State of affiliation up to the level of costs that would have been assumed had ***treatment which is*** the same or ***equally effective for the patient*** been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received. However, when the conditions set out in Article 22(2) of Regulation (EEC) No 1408/71 are fulfilled the authorisation should be granted and the benefits provided in accordance with that Regulation. This applies in particular in instances where the authorisation is granted after an administrative or judicial review of the request and that the person concerned has received the treatment in another Member State. In that case Articles 6, 7, 8 and 9 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 received a refusal of authorisation subsequently held to be unfounded, are entitled to have the cost of the treatment obtained in another Member State reimbursed in full *in accordance with* the provisions of the legislation in the Member State of treatment.

(40) Prior authorisation should only be refused in the context of a fair and transparent procedure. The rules laid down by the Member States for submitting an authorisation request and the possible reasons for refusal should be made known in advance. Refusals should be limited to what is necessary, and should be proportionate to the objectives of setting up a prior authorisation system.

(41) Patients with a life-threatening condition who are on a waiting list for medical treatment in their home country and who are in urgent need of care may not be subject to prior authorisation, as this procedure could prevent patients from having timely treatment in another Member State.

(*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 applies also to the actual reimbursement of costs of healthcare incurred in another Member State after the patient's return. It is appropriate that patients should normally have a decision regarding the cross-border healthcare within fifteen calendar days. However, that period should be shorter where warranted by the urgency of the treatment in question. In any event, recognition procedures and rules on the provision of services as provided for by Directive 2005/36/EC should not be affected by these general rules.

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(43) Appropriate information on all essential aspects of cross-border healthcare is necessary in order to enable patients to exercise their rights to cross-border healthcare in practice. For cross-border healthcare the most efficient mechanism for providing such information is to establish central contact points within each Member State to which patients can refer, and which can provide information on cross-border healthcare taking into account also the context of the health system in that Member State. Since questions about aspects of cross-border healthcare will also require liaison between authorities in different Member States, *those* central contact points should also constitute a network through which such questions can be most efficiently addressed. *Those* contact points should cooperate with each other and should enable patients to make informed choices about cross border healthcare. They should also provide information about options available in case of problems with cross-border healthcare, in particular about out of court schemes for settling cross border disputes. ***In developing arrangements for the provision of information on cross-border healthcare, the Member States should give consideration to the need to provide information in accessible formats and to potential sources of additional assistance for vulnerable patients, disabled people and people with complex needs.***

(44) When healthcare is received by a patient in a Member *State*, which is not the *Member State* where he is insured, it is essential for the patient to know in advance which rules shall be applicable. An equivalent level of clarity is needed ▌when healthcare is provided cross-border***, such as telemedicine***. In those cases, the rules applicable to healthcare are those provided by the legislation of the Member State of treatment in accordance with the general principles set out in *Article* 5 *of this Directive*, given that in accordance with *Article* 152(5) of the Treaty the organisation and delivery of health services and medical care is of responsibility of Member States. This will help the patient *to make* an informed choice, and will avoid misapprehension and misunderstanding. It will also establish a high level of trust between the patient and the healthcare provider.

(45) The Member States should decide on the form of *the* national contact points as well as the number of them. The national contact points may be also incorporated *into* 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 *for the provision of* information on the main aspects of cross-border healthcare and *for the provision of* practical assistance to patients if needed. ***The Member States should ensure the participation of bodies representing health professionals in these activities.*** 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. ***The national contact points should be able to provide patients with relevant information on cross-border healthcare and to assist them. This should not include legal advice.***

(46) ▌Cooperation ***is required*** between providers, purchasers and regulators of different Member States at national, regional or local level in order to ensure safe, high-quality and efficient care across borders. This is particularly the case for cooperation in border regions, where cross-border provision of ***healthcare*** may be the most efficient way of organising ***healthcare*** for the local populations, but where achieving such cross-border provision on a sustained basis requires cooperation between the health systems of different Member States. Such cooperation may concern joint planning, mutual recognition or adaptation of procedures or standards, interoperability of respective national information and communication technology systems, practical mechanisms to ensure continuity of care or practical *facilitation* of cross-border provision of healthcare by health professionals on a temporary or occasional basis. ▌

(47) The Commission should encourage cooperation between the Member States in the areas set out in Chapter IV of this Directive and may, in accordance with Article 152(2) of the Treaty take, in close contact with the Member States, any useful initiative to facilitate and promote such cooperation. Particular attention should be given to the possible use of a European Grouping of Territorial Cooperation (EGTC).

(*48*) Where medicinal products are authorised within the patient's Member State *of affiliation* in accordance with 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 [1], ***including the future Directives on falsified medicinal products and pharmacovigilance,*** and have been prescribed in another Member State for an individual named patient, it should be in principle possible for such prescriptions to be recognised ***medically or in pharmacies*** and used in the patient's own Member State. The removal of regulatory and administrative barriers to such recognition is without prejudice to the need for appropriate agreement of the patients' treating physician or pharmacist in every individual case, if this is warranted by protection of human health and is necessary and proportionate to that objective. Such medical recognition should also be without prejudice to the decision of the Member State of affiliation regarding the inclusion of such medicinal products within the benefits covered by the social security system of affiliation ***and without prejudice to the validity of national pricing and payment rules***. The implementation of the principle of recognition will be facilitated by the adoption of measures necessary for safeguarding the safety of a patient, and avoiding the misuse or confusion of medicinal products.

(*49*) European reference networks should provide healthcare to all patients who have conditions requiring a particular concentration of resources or expertise, in order to provide affordable, high-quality and cost-effective care and could also be focal points for medical training and research, information dissemination and evaluation. The mechanism for identification and development of the European reference networks should be established with the aim *of organising* at European level equal access to high- level shared expertise in a given medical field for all patients as well as for health professionals.

(*50*) Technological developments in cross-border provision of healthcare through the use of information and communication technologies may result in the exercise of supervisory responsibilities by Member States being unclear, and thus can hinder the free movement of healthcare and give rise to possible additional risks to health protection through this mode of supply. Widely different and incompatible formats and standards are used for cross-border provision of healthcare using information and communication technologies throughout the Community, creating both obstacles to this mode of cross-border healthcare provision and possible risks to health protection. It is therefore necessary to provide for Community harmonisation in these areas, and to do so *by* empowering the Commission to adopt implementing measures in order to allow sufficiently rapid establishment and updating of responsibilities and standards in that area to reflect constant progress in the relevant technologies and techniques.

(51) The interoperability of e-health solutions should be achieved whilst respecting national regulations on the provision of health services adopted in order to protect the patient, including legislation on internet pharmacies, in particular national bans on mail order of prescription-only medicinal products in accordance with the case-law of the Court of Justice and Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts [2].

(*52*) Routine statistics as well as complementary data on cross-border healthcare are required for efficient monitoring, planning and management of healthcare in general and cross-border healthcare in particular, and their production should be integrated *as* far as possible within existing data collection systems to enable appropriate monitoring and planning to take account of cross-border care, including appropriate structures at Community level such as the Community statistical system and in particular 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 [3], the health information system established within the framework of the health programme established by Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008) [4] and other monitoring activities such as those carried out by the European Centre for Disease Prevention and Control established by Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control [5].

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[1] OJ L 311, 28.11.2001, p. 67. ‖
[2] ***OJ L 144, 4.6.1997, p. 19.***
[3] *OJ L 354, 31.12.2008, p. 70.*
[4] OJ L 271, 9.10.2002, p. 1.
[5] OJ L 142, 30.4.2004, p. 1.

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(53) The constant progress of medical science and health technologies presents both opportunities and challenges to the health systems of the Member States. ***However, the assessment of health technologies and the possible restriction of access to new technologies by certain decisions by administrative bodies raise a number of fundamental social issues which require contributions from a wide range of stakeholders and the establishment of a viable governance model. Accordingly any cooperation should involve not only the competent authorities of all the Member States but also all the stakeholders concerned, including health professionals and representatives of patients and industry. Moreover, this cooperation should be based on viable principles of good governance such as transparency, openness, objectivity and the impartiality of procedures.***

(54) *The measures* necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ([1]).

(55) In particular, ‖ the Commission *should be empowered* to adopt***, in collaboration with relevant experts and stakeholders,*** a list of specific criteria and conditions that European reference networks must fulfil *and* the procedure for establishing European reference networks. Since those measures are of general scope and are designed to amend non-essential elements of this Directive *by supplementing it with* new non-essential elements, they *must* be adopted in accordance with the regulatory procedure with scutiny provided for in Article 5a of Decision 1999/468/EC.

(56) Since the *objective* of this Directive, namely establishing ‖ a general framework for provision of safe, high-quality and efficient cross-border healthcare in the European Union, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the action, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. 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*.

(57) The Member State of affiliation and the Member State of treatment should by prior bilateral cooperation and in consultation with the patient ensure that appropriate aftercare and support is made available in either Member State following the authorised medical treatment and that clear information is made available to patients about aftercare options and costs. To do this, Member States should adopt measures to ensure that the necessary medical and social care data are transferred with due regard to patient confidentiality and that medical and social care professionals in both countries are able to consult each other to ensure the highest quality treatment and aftercare (including social support) for the patient.

(58) By facilitating the freedom of movement for patients within the European Union, this Directive is likely to lead to competition between healthcare providers. Such competition is likely to contribute to an increase in the quality of the healthcare for all and to the establishment of centres of excellence,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

GENERAL PROVISIONS

Article 1

Aim

This Directive ***lays down rules for access to safe and high-quality healthcare in another Member State and establishes cooperation mechanisms on healthcare between Member States, whilst fully respecting national competencies in the organisation and delivery of healthcare.***

In the application of this Directive, Member States shall take into account the principles of good quality care and equity.

([1]) OJ L 184, 17.7.1999, p. 23. ‖

Article 2

Scope

This Directive shall apply to provision of ***cross-border*** healthcare regardless of how it is organised, delivered and financed or whether it is public or private. ***It shall be without prejudice to the existing legal framework on the coordination of social security systems as laid down in Regulation (EEC) No 1408/71 and its successor Regulation (EC) No 883/2004***.

This Directive shall not apply to health services whose main focus is in the field of long-term care, including services provided over an extended period of time whose purpose is to support people in need of assistance in carrying out routine, everyday tasks.

This Directive shall also not apply to organ transplantation.

Article 3

Relationship *to* other Community provisions

1. This Directive shall apply without prejudice to:

(a) Directive 2005/36/EC on the recognition of professional qualifications;

(b) Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') ([1]);

(*c*) Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data and Directive 2002/58/EC *of the European Parliament and of the Council of 12 July 2002* concerning the processing of personal data and the protection of privacy in the electronic communications sector *(Directive on privacy and electronic communications)* ([2]);

(*d*) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency ([3]) and Directive 2001/83/EC on the Community code relating to medicinal products for human use;

(*e*) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use ([4]);

(*f*) Directive 96/71/EC of the European Parliament and of the Council of 16 December 1996 concerning the posting of workers in the framework of the provision of services ([5]);

(*g*) Directive 2000/43/EC ‖ implementing the principle of equal treatment between persons irrespective of racial or ethnic origin;

(h) Directive 2004/113/EC implementing the principle of equal treatment between men and women in the access to and supply of goods and services;

(i) Directive 2000/78/EC establishing a general framework for equal treatment in employment and occupation;

([1]) ***OJ L 178, 17.7.2000, p. 1.***
([2]) OJ L 201, 31.7.2002, p. 37. ‖
([3]) OJ L 136, 30.4.2004, p. 1. ‖
([4]) OJ L 121, 1.5.2001, p. 34.
([5]) OJ L 18, 21.1.1997, p. 1.

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(j) Directive 2009/…/EC on implementing the principle of equal treatment between persons irrespective of religion or belief, disability, age or sexual orientation;

(*k*) Regulations on coordination of social security schemes, in particular Article 22 of Regulation (*EEC*) No 1408/71 ‖ on the application of social security schemes to employed persons and their families moving within the Community and Regulation (EC) No 883/2004 ‖ on the coordination of social security systems;

(*l*) 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) ([1]).

(m) ***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 ([2]);***

(n) ***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 ([3]);***

(o) Council Directive 92/49/EEC of 18 June 1992 on the coordination of laws, regulations and administrative provisions relating to direct insurance other than life assurance ([4]), as regards the implementing powers conferred on the Commission.

2. ***This Directive does not address the assumption of costs of healthcare which become necessary on medical grounds during a temporary stay of insured persons in another Member State. Nor does this Directive affect patients' rights to be granted an authorisation for treatment in another Member State where the conditions provided for by the regulations on coordination of social security schemes, in particular*** Article 22 of Regulation ***(EEC)*** No 1408/71 ***and Article 20 of Regulation (EC) No 883/2004, are met.***

▌

3. Member States shall apply the provisions of this Directive in compliance with the ‖ Treaty.

Article 4

Definitions

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

(a) 'healthcare' means ***health services or goods, such as pharmaceuticals and medical devices*** provided ***or prescribed*** by ***health professionals to patients to assess, maintain or restore their state of health or prevent them from becoming ill,*** regardless of the ways in which ***they are*** organised, delivered and financed at national level or whether ***care is*** public or private;

(b) 'health data' means any information which relates to the physical or mental health of an individual, or to the provision of health services to the individual, which may include: information about the registration of the individual for the provision of health services; information about payments or eligibility for healthcare with respect to the individual; a number, symbol or particular assigned to an individual to uniquely identify that individual for health purposes; any information about the individual collected in the course of the provision of health services to the individual; information derived from the testing or examination of a body part or bodily substance; and identification of a person (healthcare professional) as provider of healthcare to the individual;

([1]) OJ L 210, 31.7.2006, p. 19.
([2]) ***OJ L 33, 8.2.2003, p. 30.***
([3]) ***OJ L 102, 7.4.2004, p. 48.***
([4]) ***OJ L 228, 11.8.1992, p. 1.***

(*c*) 'cross-border healthcare' means healthcare provided in a Member State other than that where the patient is an insured person ▌;

▌

(d) 'health professional' means a ***medical practitioner*** or a nurse responsible for general care or a dental practitioner or a midwife or a pharmacist within the meaning of Directive 2005/36/EC or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC***, or a person legally exercising healthcare activities in the Member State of treatment***;

(e) 'healthcare provider' means any ***health professional in the sense defined in (d) above*** or legal person legally providing healthcare on the territory of a Member State;

(f) 'patient' means any natural person who receives or wishes to receive healthcare in a Member State;

(g) 'insured person' means ▌a person who is insured ***under*** the provisions of ***the definition in*** Article 1(c) of Regulation (EC) No 883/2004***, or as defined in the policy conditions of private sickness insurance schemes***;

(h) 'Member State of affiliation' means the Member State where the patient is an insured person ***or the Member State where the patient resides if this Member State is not the same as the former***.

Where, due to the application of Regulation (EEC) No 1408/71 and Regulation (EC) No 883/2004 respectively, the health insurance body in the Member State of residence of the patient is responsible for the provision of benefits in accordance with the legislation of that state, then that Member State is regarded as the Member State of affiliation for the purposes of this Directive;

(i) 'Member State of treatment' means the Member State on whose territory cross-border healthcare is actually provided;

(**j**) ***'medical device' means a medical device as defined in Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [1], 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 [2] or Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices [3];***

(k) 'goods used in connection with health care' means goods which are used to preserve or improve a person's health, such as medical devices and medicines;

(*l*) 'medicinal product' means a medicinal product as defined *in* Directive 2001/83/EC;

(*m*) 'prescription' means a medicinal prescription as defined *in* Directive 2001/83/EC including prescriptions issued and transmitted electronically (ePrescriptions);

(n) 'health technology' means a medicinal product or a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare;

(*o*) 'harm' ***is defined in cross-border healthcare by reference to the existing legal framework of the Member State of treatment and understanding of what constitutes harm may vary from Member State to Member State;***

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[1] ***OJ L 169, 12.7.1993, p. 1.***
[2] ***OJ L 189, 20.7.1990, p. 17.***
[3] ***OJ L 331, 7.12.1998, p. 1.***

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(p) 'patient's medical records' or 'medical history' 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

MEMBER STATE AUTHORITIES RESPONSIBLE FOR COMPLIANCE WITH COMMON PRINCIPLES FOR HEALTHCARE

Article 5

Responsibilities of authorities of the Member State of treatment

1. The Member States of treatment shall be responsible for the organisation and the delivery of healthcare. In such a context and taking into account principles of universality, access to good quality care, equity and solidarity, they shall define clear quality standards for healthcare provided on their territory, and ensure ***compliance with existing EU legislation on safety standards, and*** that:

(a) ***when healthcare is provided in a Member State other than that where the patient is an insured person, such healthcare is provided in accordance with the legislation of the Member State of treatment;***

(b) ***healthcare referred to in point (a) is provided in accordance with standards and guidelines on quality defined by the Member State of treatment;***

(c) patients and healthcare providers from other Member States are provided with information by the national contact point of the Member State of treatment, inter alia by electronic means, on quality standards and guidelines, including provisions on supervision, and on availability, quality and safety, treatment options, prices, outcomes of the healthcare provided, accessibility for persons with disabilities and details of the healthcare provider's registration status and insurance cover or other means of personal or collective protection with regard to their professional liability;

(*d*) healthcare providers provide all relevant information to enable patients to make an informed choice ▌;

(*e*) patients have ***the*** means of making complaints and ***the right to seek*** compensation when they suffer harm arising from the healthcare they receive ***and there are mechanisms in place to guarantee remedies***;

(*f*) systems of professional liability insurance or a guarantee or similar arrangement, ▌ which are appropriate to the nature and the extent of the risk are in place for treatment provided on their territory;

(*g*) the fundamental right to privacy with respect to the processing of personal data is protected in conformity with national measures implementing Community provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC;

(*h*) patients from other Member States shall enjoy equal treatment with the nationals of the Member State of treatment, including the protection against ***direct or indirect*** discrimination ***on the grounds of racial or ethnic origin, sex, religion or belief, disability, age, or sexual orientation*** provided for *in accordance with* Community law and national legislation in force in the Member State of treatment. ***However, this Directive shall not oblige healthcare providers in a Member State either to provide healthcare to an insured person from another Member State or to prioritise the provision of healthcare to an insured person from another Member State to the detriment of a person who has similar health needs and is an insured person of the Member State of treatment;***

(i) patients who have received treatment are entitled to a written or electronic record of such treatment and of any medical advice for the continuity of their care.

2. The public authorities in the Member State of treatment shall monitor regularly the accessibility, quality and financial state of their healthcare systems on the basis of the data collected under Article 21.

3. In order to maximise patient safety the Member States of treatment and affiliation shall ensure that:

(a) patients have a means of making complaints, and are guaranteed remedies and compensation when they suffer harm arising from the healthcare they receive;

(b) the quality and safety standards of the Member State of treatment are made public in a language and format that is clear and accessible to all citizens;

(c) there is a right to continuity of care, notably by means of the forwarding of relevant medical data concerning the patient with due respect to the provisions of point (g) of paragraph 1 and pursuant to Article 15 and patients who have received treatment are entitled to a written or electronic record of such treatment and of any medical advice for the continuity of their care;

(d) in the event of complications resulting from healthcare provided abroad or if a particular medical follow-up proves necessary, the Member State of affiliation guarantees to provide healthcare equivalent to that received on its territory;

(e) they immediately and proactively inform each other about health providers or health professionals when regulatory action is taken against their registration or their right to provide services.

4. The Commission shall, in accordance with the regulatory procedure referred to in Article 22(2), adopt measures necessary for achieving a common security level of health data at national level, taking into account existing technical standards in this field.

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5. In so far as it is necessary to facilitate the provision of cross-border healthcare and taking as a basis a high level of protection of health, the Commission, in cooperation with the Member States, ***may*** develop guidelines to facilitate the implementation of paragraph 1.

6. For the purposes of this Article, Member States shall establish a transparent mechanism for the calculation of costs that are to be charged for the healthcare provided. That calculation mechanism shall be based on objective, non-discriminatory criteria known in advance and it shall be applied at the relevant administrative level in cases where the Member State of treatment has a decentralised healthcare system.

7. In view of the great importance, particularly to patients, of safeguarding the quality and safety of cross-border care, the organisations involved in drawing up standards and guidelines as referred to in paragraphs 1 and 5 shall at the minimum include patients' organisations (particularly those of a cross-border nature).

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CHAPTER III

CROSS-BORDER HEALTHCARE

Article 6

Responsibilities of authorities of the Member State of affiliation

1. Subject to the provisions of this Directive, in particular Articles 7, 8 and 9, the Member State of affiliation shall ensure that insured persons travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State, will not be prevented from receiving healthcare provided in another Member State where the treatment in question is among the benefits provided for by the legislation, ***administrative regulations, guidelines and codes of conduct of the medical professions,*** of the Member State of affiliation to which the insured person is entitled. ***Without prejudice to Regulation (EEC) No 1408/71 and, as from its date of application, Regulation (EC) No 883/2004,*** *the* Member State of affiliation shall reimburse the costs to ***the Member State of treatment or*** the insured person‖ which would have been paid for by its statutory social security system had ***equally effective*** healthcare been provided in its territory. ***If a Member State of affiliation rejects the reimbursement of this treatment, that Member State shall have to give a medical justification for its decision.*** In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided.

Patients affected by rare diseases should have the right to access healthcare in another Member State and to receive reimbursement even if the treatment in question is not among the benefits provided for by the legislation of the Member State of affiliation.

2. The costs of healthcare provided in another Member State shall be reimbursed ***or paid directly*** by the Member State of affiliation in accordance with the provisions of this Directive up to the level of costs that would have been assumed ***in respect of the same medical condition under the same conditions as laid down in paragraph 1*** in the Member State of affiliation, without exceeding the actual costs of healthcare received. ***Member States may decide to cover other related costs, such as therapeutic treatment and accommodation and travel costs.***

3. The extra costs which persons with disabilities might incur when receiving healthcare in another Member State due to one or more disabilities shall be reimbursed by the Member State of affiliation in accordance with national legislation and on the condition that sufficient documentation setting out these costs exists.

4. The Member State of affiliation may impose on a patient seeking healthcare provided in another Member State, the same conditions, criteria of eligibility and regulatory and administrative formalities***, whether set at a local, national or regional level,*** for receiving healthcare and ***assumption*** of healthcare costs as it would impose if ***that*** healthcare was provided in its territory, in so far as they are neither discriminatory nor an obstacle to freedom of movement of ***patients and goods, such as pharmaceuticals and medical devices, and are known in advance. This may include a requirement that the insured person be assessed for the purposes of applying those conditions, criteria or formalities by a health professional or healthcare administrators providing services for the statutory social security system of the Member State of affiliation, where such an assessment would also be required for accessing health services in the Member State of affiliation.***

5. ***For the purposes of this Article,*** Member States shall have a ***transparent*** mechanism for the calculation of costs that are to be ***assumed*** by the statutory social security system ***or other statutory public system*** for healthcare provided in another Member State. This mechanism shall be based on objective, non-discriminatory criteria known in advance and the costs reimbursed *in accordance with* this mechanism shall be not less than what would have been assumed had ***that*** healthcare been provided in the territory of the Member State of affiliation. ***The mechanism shall be applied at the relevant administrative level in cases where the Member State of affiliation has a decentralised healthcare system.***

6. Patients ▌receiving healthcare ***in a Member State other than their Member State of affiliation*** or seeking to receive healthcare provided in another Member State shall be guaranteed access to their medical records, in conformity with national measures implementing Community provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC. ***If the medical records are held in electronic form, patients shall have a guaranteed right to obtain a copy of, or a right of remote access to, those records. Data shall be transmitted only with the express consent in writing of the patient or the patient's relatives.***

7. The provisions of this Chapter shall not affect the conclusion of cross-border contractual arrangements for planned healthcare.

Article 7

Non-hospital care

The Member State of affiliation shall not make the reimbursement of the costs of non-hospital care provided in another Member State ***or the purchase of goods connected with healthcare which are purchased in another Member State*** subject to prior authorisation, where the cost of that care, if it had been provided in its territory, ***or of those goods, if they had been purchased in its territory,*** would have been paid for by its social security system.

Article 8

Hospital ▌care

1. For the purposes of reimbursement of healthcare provided in another Member State in accordance with this Directive, ***the definition of*** hospital care***, as established by the Member State of affiliation,*** shall ***be limited to***:

(a) *healthcare which requires overnight accommodation of the patient in question for at least one night****; or***

(b) healthcare ***which is highly specialised and/or requires use of*** cost-intensive medical infrastructure or medical equipment; or

(c) healthcare involving treatments presenting a particular risk *to* the patient or the population.

▌

2. The Member State of affiliation may provide for a system of prior authorisation for reimbursement by its social security system of the cost of hospital care provided in another Member State where the following conditions are met:

(a) had the healthcare been provided *on* its territory, it would have been assumed by the Member State's social security system; and

(b) ***the absence of prior authorisation could*** seriously undermine ***or be likely to undermine:***

(i) the financial balance of the Member State's social security system; and/or

(ii) the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the concerned Member State.

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Such a system shall be without prejudice to Regulation (EEC) No 1408/71 and, as from its date of application, Regulation (EC) No 883/2004.

3. The prior authorisation system ***shall apply without prejudice to Article 3(2) and*** shall be limited to what is necessary and proportionate***, shall be based on clear and transparent criteria***, and shall not constitute a means of arbitrary discrimination ***or an obstacle to freedom of movement of patients.***

4. Where prior authorisation has been sought and given, the Member State of affiliation shall ensure that patients are expected only to pay upfront any costs that they would be expected to pay in this manner had their care been provided in the health system of their Member State of affiliation. Member States shall seek to transfer funds directly between the funders and the providers of care for any other costs.

5. Prior authorisation application systems must be made available at a local/regional level and must be accessible and transparent to patients. The rules for application and refusal of prior authorisation must be available in advance of an application so that the application can be made in a fair and transparent way.

6. Patients seeking to receive healthcare provided in another Member State shall be guaranteed the right to apply for prior authorisation in the Member State of affiliation.

7. The Member State *of affiliation* shall make publicly available all relevant information on the prior authorisation systems introduced pursuant to the provisions of paragraph 3***, including appeal procedures in the event of a refusal to give authorisation***.

8. With regard to any request for authorisation made by an insured person with a view to receiving healthcare in another Member State, the Member State of affiliation shall ascertain whether the conditions laid down in Regulation (EC) No 883/2004 have been met, and, if so, shall grant prior authorisation pursuant to that Regulation.

9. Patients with rare diseases shall not be subject to prior authorisation.

Article 9

Procedural guarantees regarding ***cross-border healthcare***

1. The Member State of affiliation shall ensure that administrative procedures regarding ***cross-border healthcare*** related to any prior authorisation referred to in Article 8(2), reimbursement of costs of healthcare incurred in another Member State and other conditions and formalities referred to in Article 6(4), are based on objective, non-discriminatory criteria which are published in advance, and which are necessary and proportionate to the objective to be achieved. In any event, an insured person shall always be granted the authorisation pursuant to Regulations on coordination of social security referred to in *Article 3(1)(k) of this Directive* whenever the conditions of *Article* 22*(1)(c)* and *Article* 22*(2)* of Regulation *(EEC) No* 1408/71 are met.

2. Any such procedural systems shall be easily accessible and capable of ensuring that requests are dealt with objectively and impartially within ***reasonable*** time limits set out and made public in advance by the Member States.

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3. Member States of affiliation shall ensure that patients who have received prior authorisation for cross-border healthcare will only be required to make upfront or top-up payments to the healthcare systems and/or providers in the Member State of treatment, to the extent that such payments would be required in the Member State of affiliation itself.

4. Member States shall, when setting out the time limits within which requests for *cross-border healthcare* must be dealt with ***and, when considering these requests***, take into account:

(a) the specific medical condition,

(b) individual circumstances,

(c) the patient's degree of pain,

(d) the nature of the patient's disability, and

(e) the patient's ability to carry out a professional activity.

5. Prior authorisation application systems shall be made available at the level appropriate for the administration of the Member State's health service and must be accessible and transparent to patients. The rules for application and refusal of prior authorisation must be available in advance of an application so that the application can be made in a fair and transparent way.

6. Member States shall ensure that any administrative ***or medical*** decisions regarding *cross-border healthcare* are subject***, on a case-by-case basis, to a medical opinion or an*** administrative review and also capable of being challenged in judicial proceedings, which include provision for interim measures.

7. The Commission shall conduct a feasibility study into the establishment of a clearing house to facilitate the reimbursement of costs under this Directive across borders, healthcare systems and currency zones within two years of the entry into force of this Directive and shall report back to the European Parliament and the Council and, if appropriate, present a legislative proposal.

Article 10

Prior notification

Member States may offer patients a voluntary system of prior notification whereby, in return for such notification, the patient shall receive a written confirmation of the maximum amount that will be paid. That written confirmation can then be taken to the hospital of treatment and reimbursement would then be made directly to that hospital by the Member State of affiliation.

Article 11

European Patients Ombudsman

The Commission shall present a legislative proposal to establish a European Patients Ombudsman within 18 months after the entry into force of this Directive. The European Patients Ombudsman shall consider and, if appropriate, mediate on patient complaints with regard to prior authorisation, reimbursement of costs or harm. The European Patients Ombudsman shall only be engaged once all the complaint options within the relevant Member State have been exhausted.

Article 12

Information for patients concerning the use of healthcare in another Member State

1. The Member States of affiliation shall ensure that there are ***easily accessible*** mechanisms in place***, including by electronic means, promptly*** to provide patients on request with information on receiving healthcare in another Member State, ***and shall include information on patients' entitlements, on procedures for accessing those entitlements and on systems of appeal and redress if the patient is deprived of such entitlements,*** and the terms and conditions that would apply, inter alia, whenever harm is caused as a result of healthcare received in another Member State. ***This information shall be published in formats accessible to persons with disabilities. Member States shall consult stakeholders, including patients' organisations, to ensure information is clear and accessible. In information about cross-border healthcare, a clear distinction shall be made between the rights which patients have by virtue of this Directive and rights arising from regulations on coordination of social security schemes as referred to in Article 3(1)(k).***

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2. In addition to the information outlined in paragraph 1, information on health professionals and healthcare providers shall be made easily available via electronic means by the Member State in which the health professionals and healthcare providers are registered, and shall include the name, registration number and practice address of the healthcare professional, and any restrictions on their practice.

▌

Article 13

Rules applicable to healthcare provided in another Member State

1. When healthcare is provided in a Member State other than that where the patient is an insured person, ▌ such healthcare service is provided according to the legislation of the Member State of treatment in accordance with *Article* 5.

2. This *Article shall* not apply as far as the recognition of the professional qualifications is concerned.

Article 14

National contact points for cross-border healthcare

1. Member States shall designate national contact points for cross-border healthcare and communicate their names and contact details to the Commission. ***Member States shall ensure that patient organisations, sickness funds and healthcare providers are encompassed by national contact points. The national contact points shall be established in an efficient and transparent way.***

Information about the existence of the national contact points shall be disseminated across Member States, so that patients have easy access to the information.

2. The national contact points for cross-border health care may also be incorporated into existing information centres in the Member States.

3. The national contact point in the Member State of affiliation shall ▌ provide and disseminate information to patients ***and health professionals, on a website if appropriate, on receiving healthcare in another Member State, and on the terms and conditions which apply***, in particular on ***patients'*** rights related to cross-border healthcare ***as laid down in Article 6. The national contact point shall help patients to protect their rights and seek appropriate redress in the event of harm caused by the use of healthcare in another Member State.***

4. The national contact point in the Member State of treatment shall provide and disseminate information to patients, on a website if appropriate, on issues referred to in Article 5(1)(c) and on the protection of personal data, the level of accessibility to healthcare facilities for people with disabilities, procedures for complaints and means of redress available for healthcare received in the Member State of treatment. It shall in particular inform patients ***and health professionals, where necessary,*** about ***the means by which professionals and providers are regulated and the means by which regulatory action can be taken,*** the options available to settle any dispute, ***and*** help to identify the appropriate out-of-court settlement scheme for the specific case ▌.

5. The national contact point in a Member State shall cooperate closely with other competent authorities, with national contact points in other Member States, with patients' organisations and with the Commission.

6. The national contact points shall provide the information referred to in paragraphs 2 and 3 in formats easily accessible for people with disabilities.

7. The Commission shall, in accordance with the procedure referred to in Article *22*(2), adopt:

(a) measures necessary for the management of the network of national contact points provided for in this Article;

(b) the nature and type of data to be collected and exchanged within the network;

(c) guidelines on information to patients provided for in *paragraphs 2 and 3* of this Article.

CHAPTER IV

COOPERATION ON HEALTHCARE

Article 15

Duty of cooperation

1. Member States shall render such mutual assistance as is necessary for the implementation of this Directive.

2. Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level as well as through information and communication technologies, cross-border healthcare provided on a temporary or ad hoc basis and other forms of cross-border cooperation.

3. Member States, particularly neighbouring countries, may conclude agreements with one another concerning the continuation or potential further development of cooperation arrangements.

4. Member States shall guarantee that registers in which health professionals are listed can be consulted by relevant authorities of other Member States.

5. Member States shall immediately and proactively exchange information about disciplinary and criminal findings against health professionals where they impact upon their registration or their right to provide services.

Article 16

Recognition of prescriptions issued in another Member State

1. If a medicinal product is authorised to be marketed on their territory in accordance with Article 6(1) of Directive 2001/83/EC, Member States shall ensure that prescriptions issued by an authorised person in another Member State for a named patient ***in respect of that medicinal product*** can be used in their territory and that any restrictions on recognition of individual prescriptions are prohibited unless they:

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

(b) are based on legitimate and justified doubts about the authenticity or content of an individual prescription, ***or the status of the prescriber.***

The recognition of such prescription shall not affect:

(i) national rules governing prescribing and dispensing, including generic substitution;

(ii) national rules governing the reimbursement of Community cross-border prescriptions;

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(iii) any professional or ethical duty that would require the pharmacist to refuse to dispense had the prescription been issued in the Member State of affiliation.

2. For facilitating the implementation of paragraph 1, the Commission shall adopt:

(a) measures enabling a pharmacist or other health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by an authorised person *by* developing a Community prescription template, and supporting interoperability of ePrescriptions; ***data protection safeguards shall be taken into account and incorporated from the initial stage of that development process***;

(b) measures to ensure that medicinal products prescribed in one Member State and dispensed in another are correctly identified and that the information to patients concerning the product is comprehensible***, including clarity as to different names used for the same medicinal product;***

(c) ***measures to ensure, if needed, contact between the prescribing party and the dispensing party in order to ensure complete understanding of the treatment, whilst maintaining confidentiality of patient's data***.

3. Where a prescription is issued in the Member State of treatment for medicinal products which are not normally available on prescription in the Member State of affiliation, it shall be for the latter to decide whether to authorise exceptionally or to provide an alternative medicinal product deemed to be as effective.

4. The measures referred to in points (a), (b) ***and (c)*** of paragraph 2 shall be adopted in accordance with the regulatory procedure referred to in Article *22*(2). ▌

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

Article 17

European reference networks

1. Member States shall facilitate the development of the European reference networks of healthcare providers***, in particular in the area of rare diseases, which shall draw on the health cooperation experience acquired within the European groupings of territorial cooperation (egtcs)***. Those networks shall at all times be open *to* new healthcare providers which might wish to join them, provided that such healthcare providers fulfil all the required conditions and criteria.

2. The objective of European reference networks shall be:

(a) to help to realise the potential of European cooperation regarding highly specialised healthcare for patients and for healthcare systems from innovations in medical science and health technologies;

(b) to contribute to the pooling of knowledge regarding sickness prevention and the treatment of major commonly occurring disorders;

(*c*) to help to promote access to high quality and cost-effective healthcare for all patients with a medical condition requiring a particular concentration of resources or expertise;

(*d*) to maximise cost-effective use of resources by concentrating them where appropriate;

(*e*) to help to share knowledge and provide training for health professionals;

(*f*) to provide quality and safety benchmarks and to help develop and spread best practice within and outside the network;

(*g*) to help Member States with an insufficient number of patients with a particular medical condition or lacking technology or expertise to provide a full range of highly specialised services of the highest quality;

(h) to implement instruments which enable the best possible use to be made of existing healthcare resources in the event of serious accidents, particularly in cross-border areas.

3. The Commission***, in collaboration with relevant experts and stakeholders,*** shall adopt:

(a) a list of specific criteria and conditions that the European reference networks must fulfil, including ***also a list of rarer disease areas to be covered and*** the conditions and criteria required from healthcare providers wishing to join the European reference networks, in order to ensure, in particular, that the European reference networks:

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

(ii) have sufficient capacity and activity to provide relevant services and maintain quality of the services provided;

(iii) have capacity to provide expert advice, diagnosis or confirmation of diagnosis, to produce and adhere to good practice guidelines and to implement outcome measures and quality control;

(iv) can demonstrate a multi-disciplinary approach;

(v) provide high level of expertise and experience documented through publications, grants or honorific positions, teaching and training activities;

(vi) provide strong contribution to research;

(vii) are involved in epidemiological surveillance, such as registries;

(viii) have close links and collaboration with other expert centres and networks at national and international level and capacity to network;

(ix) have close links and collaboration with patients associations where such associations exist;

(x) have appropriate and effective relationships with technology providers.

(b) the procedure for establishing European reference networks.

4. The measures referred to in paragraph 3, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article *22*(3).

Article 18

Trial areas

The Commission, in cooperation with the Member States, may designate border regions as trial areas in which innovative cross-border healthcare initiatives can be tested, analysed and evaluated.

Article 19

E-health

The Commission shall, in accordance with the procedure referred to in Article *22*(2), adopt specific measures necessary for achieving the interoperability of information and communication technology systems in the healthcare field, applicable whenever Member States decide to introduce them. Those measures shall ***conform to the applicable data protection laws in each Member State and shall also*** reflect developments in health technologies and medical science, ***including telemedicine and telepsychiatry,*** and respect the fundamental right to the protection of personal data ▌.They shall specify in particular the necessary standards and terminologies for inter-operability of relevant information and communication technology systems to ensure safe, high-quality and efficient provision of cross-border health services.

The Member States shall ensure that the use of e-Health and other telemedicine services:

(a) adhere to the same professional medical quality and safety standards as those in use for non-electronic healthcare provision;

(b) offer adequate protection to patients, notably through the introduction of appropriate regulatory requirements for practitioners similar to those in use for non-electronic healthcare provision.

Article 20

Cooperation on management of ▌health technologies

1. ***The Commission shall, in consultation with the European Parliament, facilitate the establishment*** of a network connecting the national authorities or bodies responsible for health technology assessment. ***That network shall be based on the principles of good governance including transparency, objectiveness, fairness of procedures, and broad and full stakeholder participation of all relevant groups, including - but not limited to - health professionals, patients' representatives, social partners, scientists and industry, whilst respecting Member States' competence in the area of health technology assessment.***

2. The objective of the health technology assessment network shall be:

(a) to support cooperation between national authorities or bodies;

(b) to find sustainable ways to balance the objectives of access to medicines, reward for innovation and management of healthcare budgets;

(c) to support provision of objective, reliable, timely, transparent and transferable information on the short- and long-term effectiveness of health technologies and enable an effective exchange of this information between national authorities or bodies;

(d) to analyse the nature and type of information that can be exchanged.

3. Member States shall designate the authorities or bodies participating in the network as referred to in paragraph 1 and communicate to the Commission *the* names and contact details of those authorities or bodies.

4. The Commission shall, in accordance with the *regulatory* procedure referred to in *Article 22(2)*, adopt the necessary measures for the establishment, the management ***and the transparent functioning*** of this network ▌.

5. The Commission shall only allow such authorities to join the network which fulfil the principles of good governance as defined in paragraph 1.

Article 21

Data collection for statistical and monitoring purposes

1. Member States shall collect statistical ▌data needed for monitoring purposes on the provision of cross-border healthcare, the care provided, its providers and patients, the cost and the outcomes. They shall collect such data as part of their general systems for collecting healthcare data, in accordance with national and Community law for the production of statistics and on the protection of personal data***, and specifically Article 8(4) of Directive 95/46/EC***.

2. Member States shall transmit the data referred to in paragraph 1 to the Commission at least annually, except for data that are already collected pursuant to Directive 2005/36/EC.

3. Without prejudice to the measures adopted for the implementation of the Community Statistical Programme as well as to those adopted for the implementation of Regulation (EC) No *1338/2008*, the Commission shall, in accordance with the *regulatory* procedure referred to in *Article 22(2)*, adopt measures for the implementation of this Article.

CHAPTER V

IMPLEMENTING AND FINAL PROVISIONS

Article 22

Committee

1. The Commission shall be assisted by a Committee, consisting of representatives of the Member States and chaired by the Commission representative. ***In that process, the Commission shall ensure the consultation of experts from the relevant patient and professional groups in an appropriate manner, especially in the context of the implementation of this Directive, and shall provide a reasoned report on those consultations.***

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 of that Decision.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 3 months.

Where implementing measures relate to the processing of personal data the European Data Protection Supervisor shall be consulted.

3. Where reference is made to this paragraph, Article 5a (1) to (4), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 23

Reports

The Commission shall within five years after the date referred to in Article *25*(1) draw up a report on the operation of this Directive***, including statistics on patient outflows and inflows resulting from this Directive,*** and submit it to the European Parliament and to the Council.

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To that end and without prejudice to Article 25, the Member States shall communicate to the Commission any measure they have introduced, modified or maintained with a view to *implementing* the procedures laid down in Articles 8 and 9.

Article 24

References to other legislation

As from the date of applicability of Regulation (EC) No 883/2004 ‖:

— references to *Regulation (EEC) No* 1408/71 in this Directive shall be construed as references to Regulation *(EC) No* 883/2004;

— references to Article 22 of *Regulation (EEC) No* 1408/71 in this Directive shall be construed as references to Article 20 of Regulation *(EC) No* 883/2004.

Article 25

Transposition

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by … (*).

They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 26

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 27

Addressees

This Directive is addressed to the Member States.

Done at … ‖,

For the European Parliament
The President

For the Council
The President

(*) *One year after the date of entry into force of this Directive.*