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Proposal for a

**DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

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

(presented by the Commission)

{SEC(2008) 2163}

{SEC(2008) 2164}

{SEC(2008) 2183}

## **EXPLANATORY MEMORANDUM**

### **1. BACKGROUND AND PREPARATORY WORK**

In 2003 health ministers and other stakeholders invited the Commission to explore how legal certainty in the field of cross-border care could be improved following the Court of Justice jurisprudence concerning the right of patients to benefit from medical treatment in another Member State<sup>1</sup>. The Court's rulings on the individual cases are clear in themselves, however, it is necessary to improve clarity to ensure a more general and effective application of freedoms to receive and provide health services. The Commission's proposal for a Directive on services in the internal market at the start of 2004 therefore included provisions codifying the rulings of the Court of Justice in applying free movement principles to health services. This approach, however, was not accepted by the European Parliament and Council. It was felt that specificities of health services were not sufficiently taken into account, in particular their technical complexities, sensitivity for public opinion and major support from public funds. The Commission therefore developed a policy initiative specifically targeting healthcare services as a separate issue.

The Council adopted in June 2006 conclusions on Common values and principles in EU Health Systems in which it stated that it believes there is particular value in any appropriate initiative on health services ensuring clarity for European citizens about their rights and entitlements when they move from one EU Member State to another and in enshrining values and principles in a legal framework in order to ensure legal certainty<sup>2</sup>.

The European Parliament contributed to the discussions concerning cross-border healthcare with various reports. The Parliament adopted in April 2005 a report on patient mobility and healthcare developments in the European Union<sup>3</sup>, in March 2007 a resolution on Community action on the provision of cross-border healthcare<sup>4</sup> and in May 2007 a report on the impact and consequences of the exclusion of health services from the Directive on services in the internal market<sup>5</sup>.

Stakeholders have been also extensively involved in Commission activities regarding patient mobility and health care over many years, in particular through the High Level Reflection Process, the Open Forum<sup>6</sup> and the High Level Group on Health Services and Medical care<sup>7</sup>.

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<sup>1</sup> See the Report of the High Level Process of Reflection on patient mobility and healthcare developments in the European Union and the Commission Communication on the follow-up to the high level reflection process on patient mobility and healthcare developments in the European Union, COM (2004) 301 final, 20 April 2004.

<sup>2</sup> 10173/06 SAN 168 SOC 302 MI 132

<sup>3</sup> A6-0129/2005 final

<sup>4</sup> B6-0098/2007

<sup>5</sup> A6-0173/2007 final

<sup>6</sup> The last Open Health Forum attracted around 380 participants from a wide range of health organisations. The Forum recommended during its conference in November 2005 that the Commission should address the potential of targeted healthcare legislation, because subsidiarity is not a sufficient guarantee of meeting the promise of universal access to high quality healthcare. The Forum also confirmed the need for strong and fully implemented safeguards of patient safety at EU level whilst respecting for the capacity of national rules guaranteeing quality and safety. The Forum also recommended to establish an internet portal for the free exchange of data, evidence and practice to foster continuous learning and innovation, Final Report of the Open Health Forum, Health challenges and future strategy, European Public Health Alliance (2005).

Consultation on the specific initiative on cross-border healthcare started formally in September 2006 with the publication of a Communication<sup>8</sup> inviting all relevant stakeholders to contribute to a consultation process regarding Community action on health services. The objective of the consultation was to clearly identify the problems and to get input concerning objectives and policy options. The Communication as well as the full summary report of the responses<sup>9</sup> was published on the Commission website<sup>10</sup>.

The Commission received 280 responses to this consultation from a wide range of stakeholders, including health professional organisations, health care providers, national and regional governments, insurers, the industry and individual citizens. A wide range of issues related to healthcare, and in particular to cross-border healthcare, in Europe was raised. These were taken into account in preparatory work on this Commission proposal.

This proposal is also based on several external surveys, analyses and studies conducted in the past years. In particular, the European Observatory on Health Systems and Policies provided an independent expert analysis<sup>11</sup>, which was used especially in support of the impact assessment of this proposal. This analysis was taking stock of developments on health care in Europe, focussing on seven aspects of cross-border health care: pre-authorization and access to healthcare; quality and safety; patient rights; cross-border collaboration; health care baskets and tariffs; past impacts of cross-border healthcare; and cross-border healthcare data. This exercise was based on existing research, supported largely by the European Commission, examples and studies with the aim to provide better understanding of cross-border health care from different national health systems perspectives on the above mentioned aspects and describes how current legal and non-legal uncertainties have had an impact on cross-border health care in general and the aspects mentioned above in particular (now and in the past), who is affected, in what ways, and to what extent.

## 2. ELEMENTS OF THE COMMUNITY FRAMEWORK FOR CROSS-BORDER HEALTHCARE

The Commission proposes the establishment of a Community framework for cross-border healthcare, as set out in this proposal for a directive. As well as setting out relevant legal definitions and general provisions, this is structured around three main areas:

- **common principles in all EU health systems**, as agreed in June 2006 by the Council, setting out which Member State shall be responsible for ensuring the common principles for healthcare and what those responsibilities include, in order to ensure that there is clarity and confidence with regard to which authorities are setting and monitoring healthcare standards throughout the EU;

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<sup>7</sup> All EU Member States are represented in the High Level Group on Health Services and Medical Care, observers from the EEA/EFTA states as well as representatives from civil society have also been involved in the work of this group; Report on the work of the High Level Group on Health Services and Medical Care in 2006, European Commission (2006).

<sup>8</sup> Commission Communication, Consultation regarding Community action on health services, SEC (2006) 1195/4, 26 September 2006.

<sup>9</sup> Commission document, Summary report of the responses to the consultation regarding "Community action on health services" (2007)

<sup>10</sup> [http://ec.europa.eu/health/ph\\_overview/co\\_operation/mobility/results\\_open\\_consultation\\_en.htm](http://ec.europa.eu/health/ph_overview/co_operation/mobility/results_open_consultation_en.htm)

<sup>11</sup> Wismar M, Palm W, Figueras J, Ernst K and Van Ginneken E, Cross-Border Healthcare: Mapping and Analysing Health Systems Diversity, European Observatory on Health Systems and Policies, 2007.

- **a specific framework for cross-border healthcare:** the directive will make clear the entitlements of patients to have healthcare in another Member State, including the limits that Member States can place on such healthcare abroad, and the level of financial coverage that is provided for cross-border healthcare, based on the principle that patients are entitled to obtain reimbursement up to the amount that would have been paid had they obtained that treatment at home;
- **European cooperation on healthcare:** the directive establishes a framework for European cooperation in areas such as cooperation in border regions, recognition of prescriptions issued in other countries, European reference networks, health technology assessment, data collection and quality and safety, in order to enable the potential contribution of such cooperation to be realised effectively and on a sustained basis.

Based on the case-law, this initiative aims at ensuring a clear and transparent framework for the provision of cross-border healthcare within the EU, for those occasions where the care patients seek is provided in another Member State than in their home country. When this happens, there should be no unjustified obstacles. The care should be safe and of good quality. The procedures for reimbursement of costs should be clear and transparent. While respecting principles of universality, access to quality care, equity and solidarity, the objectives of this framework will therefore be to:

- provide sufficient clarity about rights to be reimbursed for healthcare provided in other Member States;
- and ensure that the necessary requirements for high-quality, safe and efficient healthcare are ensured for cross-border care.

### **3. COHERENCE WITH OTHER COMMUNITY POLICIES**

#### **a) Regulations for coordination of social security schemes**

This proposal would not modify the existing framework for coordination of social security schemes and this framework will remain in place with all the general principles on which the regulations on coordination of social security schemes are based, including putting the patient receiving healthcare in another Member State on the equal footing with the residents of that Member State, and the existing European Health Insurance Card. In terms of patients seeking planned healthcare in another Member State, this ensures that if the appropriate care for the patients' condition cannot be provided in their own country without undue delay, then they will be authorised to go abroad, and any additional costs of treatment will be covered by public funds. The mechanism for this is already in place through the regulations on coordination of social security systems<sup>12</sup>, and this will continue to be the case.

The new directive on cross-border healthcare would put in place an alternative mechanism based on the principles of free movement and building on the principles underlying decisions of the Court of Justice. This would allow patients to seek any healthcare in another Member

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<sup>12</sup> Council Regulation (EC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community. OJ L 149, 5.7.1971, p.2.

State that they would have been provided at home and be reimbursed up to the amount that would have been paid had they obtained that treatment at home, but they bear the financial risk of any additional costs arising.

Provisions regarding entitlements provided for by this proposal and provisions regarding entitlements provided for by the Regulation (EC) No. 1408/71 are alternative mechanisms for the assumption of the cost of cross-border healthcare. When the prior authorisation is sought and granted within the framework provided for by the Regulation (EC) No. 1408/71, the provisions of that Regulation apply and sickness benefits are granted according to the rules established by that Regulation. This would be the case in particular for treatment provided through European reference networks as provided for in the directive. When the costs of healthcare are reimbursed according to Chapter III of this Directive, the provisions of the Directive apply. However, an insured person shall always be granted the authorisation pursuant to Regulations on coordination of social security referred to in Art. 3.1 f) whenever the conditions of Art.22.1 c) and Art.22.2 of Regulation 1408/71 are met.

#### **b) Framework for mutual recognition of professional qualifications**

This proposal would also apply without prejudice to the existing framework for mutual recognition of professional qualifications established by the Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications<sup>13</sup>. The Directive 2005/36/EC establishes rules according to which a Member State which makes access to or pursuit of a regulated profession, including health professions, in its territory contingent upon possession of specific professional qualifications shall recognise professional qualifications obtained in an other Member State which allow the holder of those qualifications to pursue the same profession there. This proposal does not aim to amend, modify or otherwise interfere with the existing rules on the mutual recognition of professional qualifications. Neither should any measure, taken by Member States in view of implementing this proposal by ensuring that healthcare is provided according to clear quality and safety standards, constitute new barriers to the free movement of health professionals as regulated by Directive 2005/36/EC.

#### **c) Community framework for protection of personal data**

The EU framework provided by the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data<sup>14</sup> and Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector<sup>15</sup> guarantees to patients rights related to privacy with respect to the processing of personal data and this proposal is without prejudice to this existing framework. Ensuring continuity of cross-border healthcare depends on timely transfer of data concerning patient's health. The framework provided by 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, provides for patient's right to have access to his personal data concerning his health. This includes also right to access to the patient's medical records, such as diagnosis, examination results, assessments by treating physicians and any treatment or interventions provided. This directive should be therefore

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<sup>13</sup> OJ L 255, 30.9.2005, p. 22.

<sup>14</sup> OJ L 281, 23.11.1995, p.31.

<sup>15</sup> OJ L 201, 31.7.2002, p. 37.

without prejudice to this Community framework established by those directives and the national laws implementing those directives.

**d) E-health**

This proposal is also without prejudice to the existing framework provided for by the 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)<sup>16</sup>. That directive contributes to the functioning of the internal market by ensuring the free movement of information society services, including e-Health services, between the Member States. That directive stipulates information requirements on the information society services providers, rules on commercial communications, rules regarding contracts concluded by electronic means and liability of intermediary services providers. The existing framework shall remain in place and this proposal applies only insofar as the measures are not already covered by the Directive 2000/31/EC.

**e) Racial equality**

This proposal applies in conformity with the Council Directive 2000/43/EC of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin. That Directive prevents people in the European Union from being discriminated against on grounds of race and ethnic origin and is also applicable to all persons, in relation to social protection, including social security and healthcare (see art.3.1 e). Therefore, the principle of equal treatment enshrined in Directive 2000/43/EC which means that there shall be no direct or indirect discrimination based on racial or ethnic origin shall remain in place and is not affected by the provisions of this Directive.

**4. GENERAL LEGAL ASPECTS**

**a) Legal basis**

The proposal for a directive is based on Article 95 of the Treaty. This legal base is justified by both the objective and the content of the proposal. Measures adopted under Article 95 of the Treaty should have as their object the establishment and functioning of the internal market. The aim of this proposal is to establish a general framework for provision of safe, high quality and efficient cross-border healthcare in the European Union and to ensure free movement of health services and a high level of health protection, whilst fully respecting the responsibilities of the Member States for the organisation and delivery of health services and medical care. The objective of this proposal is therefore fully in line with the requirements of both Articles 95 and 152 of the Treaty.

The Court's rulings on the individual cases outlined above are clear in themselves, and no pre-condition may be required for the exercise of the rights of patients recognised by the Court. However, it is necessary to ensure a more general and effective application of these internal market rights in practice, and to ensure that they can be exercised in a way which is compatible with overall health system objectives of accessibility, quality and financial sustainability. The Court has held that the freedom to provide services includes the freedom

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<sup>16</sup> OJ L 178, 17.7.2000, p. 1.

for the recipients of services, including persons in need of medical treatment, to go to another Member State in order to receive those services there<sup>17</sup>. As the Court has also held, the fact that the legislation of the Member State of affiliation does not guarantee a patient covered by that legislation a level of reimbursement equivalent to that to which he would have been entitled if he had received healthcare in the Member State of affiliation is a restriction of the freedom to provide services within the meaning of Article 49 EC<sup>18</sup>. It is therefore necessary to address issues in the Directive related to the reimbursement of the cost of healthcare provided in other Member States in order to facilitate the right to provide and obtain health services.

Moreover, whenever healthcare is provided, it is vital for patients to ensure:

- clear information that enables people to make informed choices about their healthcare;
- mechanisms for ensuring the quality and safety of the healthcare that is provided;
- continuity of care between different treating professionals and organisations;
- and mechanisms to ensure appropriate remedies and compensation for harm arising from healthcare.

However, there are no clear rules at Community level about how these requirements should be met for cross-border healthcare, or who is responsible for ensuring that they are. This is the case no matter how the care is paid for – whether it is paid for publicly or privately, whether it is undertaken through the regulations on coordination of social security systems or whether it is in application of the additional free movement rights described above.

It is often difficult for patients and professionals to identify what rights exist for reimbursement for cross-border healthcare. This was confirmed by a Eurobarometer survey<sup>19</sup> which showed that 30% of the citizens in the European Union are not aware of the possibility to receive healthcare outside their country of affiliation. This uncertainty and confusion about the general application of rights to reimbursement for healthcare provided in other Member States is likely to make it more difficult for patients to use their rights in practice, as those responsible will be reluctant to implement rules and procedures when they are not clear about what they are. And if patients wish to contest the interpretations that are given or the rules being applied, it is difficult for them to do so in the absence of clarity about what their rights are and how they should exercise them.

The objective of this initiative is therefore to ensure that there is a clear framework for cross-border healthcare within the EU in order to enable the rights of the patients to be exercised whilst ensuring a high level of health protection, by:

- providing sufficient clarity about rights to be reimbursed for healthcare provided in other Member States for those rights to be realised in practice;
- and ensuring that the necessary requirements for high-quality, safe and efficient healthcare are also ensured for cross-border care;

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<sup>17</sup> See in particular Case C-158/96 Kohll, paragraphs 35-36.

<sup>18</sup> See in particular Case C-368/98 Vanbraekel, paragraph 45.

<sup>19</sup> Flash Eurobarometer Series #210, Cross-border health services in the EU, Analytical report, conducted by The Gallup Organization, Hungary upon the request of the European Commission, the Health and Consumer Protection Directorate-General (DG SANCO), 2007.



whilst ensuring that such cross-border healthcare is compatible with the overall objectives of the Member States of ensuring accessibility, quality and safety of the healthcare that their health systems provide. In particular, the proposal ensures that the impact of cross-border healthcare under this proposal does not undermine health and social security systems, either through its direct financial impact or through its impact on overall planning and management of those systems.

This proposal respects the fact that health systems are primarily the responsibility of Member States and fully respects the responsibilities of the Member States for the organisation and delivery of health services and medical care in accordance with Article 152 TEC. Article 95(3) of the Treaty further stipulates that the Commission, in its proposals for the establishment and functioning of the internal market concerning health, shall take as a basis high level of protection of health, taking account in particular of any new development based on scientific evidence. In preparation of this proposal, the Commission took fully into account the most recent research results and the current best medical practice. Several expert studies, analyses and research reports were used in the preparatory work. The proposal will thus ensure that the necessary requirements for high-quality, safe and efficient healthcare are also ensured for cross-border healthcare.

## **b) Subsidiarity**

The overall objective of this initiative is to ensure that there is a clear framework for cross-border healthcare within the EU, in order to provide sufficient clarity about rights to be reimbursed for healthcare provided in other Member States for those rights to be realised in practice; and to ensure that the necessary requirements for high-quality, safe and efficient healthcare are also ensured for cross-border care.

Issues requiring greater clarity and certainty regarding Community law in this area cannot be addressed by the Member States alone. Action by Member States alone or lack of Community action would significantly undermine both the safe and efficient provision of cross-border healthcare, and would leave Member States without a clear capacity to manage and steer their health systems as a whole, as emphasised by several Member States during the consultation. Cross-border healthcare has, as the name already predicts, many Community-wide trans-national aspects. Both national government and individual citizens face in this field challenges that cannot be satisfactorily solved by Member States alone.

According to Article 152(5) of the EC Treaty Community action in the field of public health is to fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. As confirmed by the Court<sup>20</sup>, that provision does not, however, exclude the possibility that the Member States may be required under other Treaty provisions, such as Article 49 EC of the EC Treaty, or Community measures adopted on the basis of other Treaty provisions, to make adjustments to their national healthcare and social security systems. As the Court held, this does not mean that this undermines their sovereign powers in the field.

In any event, Member States are responsible for the organisation and delivery of health services and medical care. They are in particular responsible for determining which rules will apply to the reimbursement of patients and to the provision of health care. This proposal changes nothing in this respect. It is important to underline that this initiative does not alter

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<sup>20</sup> See Case C-372/04 Watts, paragraph 147.

the Member States' choice of the rules which will be applicable to a specific case. Instead, this framework is designed to facilitate European cooperation on healthcare, such as for European networks of centres of reference; sharing assessments of new health technologies; or using information and communication technology to provide more efficient healthcare ("e-health"). By doing so, this will provide additional support to the Member States in achieving their overall objectives of universal access to high-quality healthcare on the basis of equity and solidarity, which will benefit all patients, whether they move countries or not.

Since the objectives of this proposal 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, this proposal complies with the principle of subsidiarity as set out in Article 5 of the EC Treaty.

### **c) Proportionality**

In accordance with the principle of proportionality, as set out in Article 5 of the Treaty, the Community action shall not go beyond what is necessary in order to achieve those objectives. This proposal sets out only general principles creating the EU framework, but leaves a wide margin for implementation of these principles by the Member States according to their national, regional or local circumstances. Moreover, this proposal fully respects responsibilities of the Member States to organise, finance and deliver health services and medical care. The proposal does not change the right of Member States to define the healthcare benefits that they choose to provide to their citizens. If a Member State does not include a particular treatment as part of the entitlement of their citizens at home, this mechanism does not create any new entitlement for patients to have such treatment abroad and be reimbursed. Moreover, this also does not alter the right of Member States to apply conditions to their benefits, such as going through a general practitioner for referral to specialist treatment. This proposal thus complies also with the principle of proportionality as set out in Article 5 of the EC Treaty.

## **5. CHAPTER I**

### **5.1. Aim of the directive**

The overall aim of this proposal is to ensure that there is a clear framework for cross-border healthcare within the EU. This requires action to address barriers to the provision of cross-border healthcare and which present risks for a high level of health protection.

The uncertainty about the general application of rights to reimbursement for healthcare provided in other Member States is creating obstacles to the free movement of patients and of health services more generally in practice. This is shown both by the research and consultation which preceded these proposals, including surveys of citizens which identify wide degrees of uncertainty, and a high number of patients who should have been entitled to reimbursement for cross-border healthcare but who did not claim it.

Whenever healthcare is provided, it is vital for patients to ensure:

- clear information that enables people to make informed choices about their healthcare;

- mechanisms for ensuring the quality and safety of the healthcare that is provided;
- continuity of care between different treating professionals and organisations;
- and mechanisms to ensure appropriate remedies and compensation for harm arising from healthcare.

## **5.2. Scope of the directive**

The proposed directive applies to all healthcare provision, regardless of how it is organised, delivered or financed. It is impossible to know in advance whether a given healthcare provider will supply healthcare to a patient coming from other Member States or to patients from its own Member State, it appears necessary that the requirements to ensure that healthcare is provided according to clear quality and safety standards are applicable to all health services, without discrimination between different types of organisation, delivery or financing of the provision of that healthcare.

## **6. CHAPTER II - MEMBER STATE AUTHORITIES RESPONSIBLE FOR COMPLIANCE WITH COMMON PRINCIPLES FOR HEALTHCARE**

### **6.1. Responsibilities of authorities of the Member State of treatment**

As set out above, ensuring compliance with common healthcare principles for cross-border healthcare is essential for ensuring free movement of health services. The combination of variety between systems and lack of clarity about the responsibilities of different authorities could act as an obstacle to cross-border healthcare, as shown by research and evaluation including existing examples of cross-border healthcare and uncertainties of citizens reported through surveys<sup>21</sup>.

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, it is necessary that the requirements to ensure that healthcare is provided according to common principles and clear quality and safety standards are applicable to all healthcare services in order to ensure the freedom to provide and obtain cross border healthcare which is the aim of the directive.

This implies two elements. The first is clarity over which is the Member States who should be responsible in any given case of cross-border healthcare for ensuring compliance with common principles for healthcare.. There was clear consensus from the consultation that preceded these proposals that greater clarity was needed on this point, and that the most appropriate choice would be to make clear that it is the authorities of the Member State in which the treatment is provided that should be responsible for ensuring that common principles are met also in the case of cross-border healthcare.

However, this is not sufficient in itself. The second element is therefore a minimum degree of certainty about what the authorities of the responsible Member State will

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<sup>21</sup> See the impact assessment, and the results of the Europe 4 Patients research project referred to above.

ensure for all healthcare on their territory. Whilst respecting the wide variety of different systems, structures and mechanisms put in place by the Member States in this area, this will ensure a minimum core set of common principles on which patients and professionals from other Member States know they can rely.

It remains up to Member States to decide on the standards for healthcare in their country. It does not interfere in the ability of Member States to organise their health systems as they wish. In order to ensure that the degree of harmonisation that this implies remains proportionate, the principles in the directive take as a basis the Council conclusions on "Common values and principles in European Union Health Systems" of June 2006, and therefore should not require major adaptations of existing systems. The Commission will develop guidelines to facilitate the implementation of these principles.

As set out in those common values and principles, different Member States have different approaches to making a practical reality of these values: they have, for example, different approaches to questions such as whether individuals should pay a personal contribution towards the cost of elements of their health care, or whether there is a general contribution, and whether this is paid for from supplementary insurance. Member States have implemented different provisions to ensure equity: some have chosen to express it in terms of the rights of patients; others in terms of the obligations of healthcare providers. Enforcement is also carried out differently — in some Member States it is through the courts, in others through boards, ombudsmen, or other mechanisms.

The directive still provides Member States with the freedom to organise their health systems as they wish in order to achieve these common principles, in compliance with Article 152, paragraph 5 EC. The aim of this framework is simply to make clear which is the Member State that is responsible in any given situation, to avoid gaps or overlaps, and to clarify what those responsibilities mean in practice. The common principles set out in the directive are as follows:

- the first three common principles (the clear definition by authorities of Member States of standards for quality and safety of care, transparency about applicable standards for patients and professionals, mechanisms to ensure the translation of those standards into practice, and monitoring) are intended to ensure that the fundamental elements for ensuring quality and safety of healthcare are in place. These elements establish the basic elements to be able to give patients and professionals confidence about the quality and safety of healthcare provision through all patients and health providers operating on the basis of a common core of general obligations;
- if patients cannot have access to the key medical, financial and practical information relevant to the healthcare that they are seeking, this clearly would constitute an obstacle to their freedom to receive health services in another Member State by making it difficult for patients to make a rational and informed choice between different providers including providers in other Member States;
- Member States have to set up procedures and systems to be used in case of harm caused when healthcare is provided. It is clear that patients are aware that healthcare can go wrong; across the EU, 78% of citizens consider medical errors

to be an important problem. This concern is not unfounded; research suggests that harm arises from healthcare in 10% of cases. Ensuring clear common obligations to deal with circumstances of responding to harm arising from healthcare is therefore essential to avoid lack of confidence in those mechanisms acting as an obstacle to taking up cross-border healthcare.

- The Member State of treatment also has to ensure that mechanisms for patients to seek redress and compensation if they suffer harm as a result of receiving cross-border healthcare are in place. However, it is for the Member State to determine the nature and modalities of such mechanisms, for example through professional liability insurance, or a guarantee or similar arrangement which is equivalent or essentially comparable as regards its purpose. This requirement should ensure at least equivalent protection for provision of healthcare to patients residing in other Member States. Such arrangements should be appropriate to the nature and the extent of the risk, in order to avoid this requirement being disproportionate in the context of the provision of cross-border healthcare and have due regard to guarantees that are already in place in healthcare provider's home Member State, where these are different.
- ensuring continuity of healthcare requires transfer of the relevant health data and in particular a patient's medical records, but this is clearly a very sensitive issue. The consultation showed widespread uncertainty about how this can be ensured in practice when transferring health data to other countries, with concern over ensuring protection of personal data sometimes hindering appropriate transfer of data that is essential for continuity of care. It is therefore vital to ensure confidence that privacy and protection of personal data will also be respected for health data transferred to another Member State, both to avoid lack of confidence acting as a barrier to free movement of health services, and to avoid lack of transfer of data undermining continuity of care and thus creating additional risks to health protection;
- and in order to avoid unsustainable impacts of healthcare, it is important to ensure that patients from within and outside domestic systems are treated in a non-discriminatory manner. From an economic point of view, this avoids either perverse incentives to prioritise patients from abroad ahead of domestic patients, or long-term undermining of capital investment in health. From a health perspective, treating patients equitably is essential to ensure that the health impact of cross-border healthcare on health consequences such as waiting times remains reasonable and manageable. Moreover, according to the general principles of equity and non discrimination, patients 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.. Furthermore, as this Directive respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union, it has to be implemented and applied with due respect for the rights 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..

## 7. CHAPTER III – USE OF HEALTHCARE IN ANOTHER MEMBER STATE

### 7.1. Healthcare provided in another Member State

The right to reimbursement of the costs of healthcare provided in another Member State from the statutory social security scheme of patients as insured persons was recognised by the Court of Justice in several judgements<sup>22</sup>. The Court has held that the freedom to provide services includes the freedom for the recipients of services, including persons in need of medical treatment, to go to another Member State in order to receive those services there<sup>23</sup>. It has to be remembered that all the case-law of the Court of Justice in this matter are based on referrals initiated by single citizens trying to exercise individual rights stemming from the EC Treaty itself.

As the Court has also held, the fact that the legislation of the Member State of affiliation does not guarantee a patient covered by that legislation a level of reimbursement equivalent to that to which he would have been entitled if he had received healthcare in the Member State of affiliation is a restriction of the freedom to provide services within the meaning of Article 49 EC<sup>24</sup>. From the research and consultation preceding these proposals, a certain degree of uncertainty exists about the general application in practice of the rights deriving from these judgements, which acts as a barrier to the free movement of services. It is therefore necessary to address issues in the Directive related to the reimbursement of the cost of healthcare provided in other Member States in order to facilitate the right to provide and obtain health services. Provisions of Article 6 and 7, and partly also Articles 8 and 9 therefore provide for reimbursement of costs in case of healthcare provided in another Member State, in order to facilitate the provision of healthcare services.

This Directive does not provide neither for transfer of social security entitlements between Member States nor for coordination of social security schemes. The only social security system concerned by the provisions of Chapter III of the directive is the social security system of the Member State where the patient is insured, and the only entitlements covered by Chapter III are the entitlements provided in accordance with the social security system of the patient's Member State of affiliation. The provisions regarding access to and reimbursement of healthcare provided in another Member State are introduced to enable patients and healthcare providers freedom to receive and to provide healthcare and to remove unjustified obstacles to that fundamental freedom within the patient's Member State of affiliation.

This proposal does not change the right of Member States to define the benefits that they choose to provide. If a Member State does not include a particular treatment as part of the entitlement of their citizens at home, this directive does not create any new entitlement for patients to have such treatment abroad and be reimbursed. In addition, the proposal does not prevent the Member States from extending their benefits-in-kind schemes to healthcare provided abroad, a possibility already

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<sup>22</sup> See in particular Case C-158/96 *Kohll* [1998] ECR I-1931, Case C-120/95 *Decker* [1998] ECR I-1831, Case C-368/98 *Vanbraekel* [2001] ECR I-5363; Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473; Case C-56/01 *Inizan* [2003] ECR I-12403; Case C-8/02 *Leichtle* [2004] ECR I-2641; Case C-385/99 *Müller-Fauré and Van Riet* [2003] ECR I-4503, and Case C-372/04 *Watts* [2006] ECR I-4325.

<sup>23</sup> See in particular *Kohll*, paragraphs 35-36.

<sup>24</sup> See in particular *Vanbraekel*, paragraph 45.

implemented by several Member States. The evidence available as set out in the impact assessment 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 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.

In the light of the case-law of the Court of Justice, it is not appropriate to establish or maintain the requirement of any prior authorisation for reimbursement by the 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 prior authorisation requirement will not undermine the financial equilibrium of social security systems<sup>25</sup>. As regards hospital care, the Court of Justice has however 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.

Therefore this Directive does not introduce a general prior authorisation requirement but allows Member States to provide for a system of prior authorisation for assumption of costs for hospital care provided in another Member State, provided however, that Member States can provide evidence that 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 this 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 concerned Member.

In such cases, and according to the relevant jurisprudence, the introduction of a prior authorisation scheme, which will limit the exercise of rights conferred upon the citizens directly by the EC Treaty, must be proportionate and justified by imperative reasons as those mentioned in the same case-law. In some instances, Member States may not have an existing set of defined reimbursement levels for particular types of care (for example, in health systems with integrated public financing and provision).

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<sup>25</sup> See in particular *Kohll*, paragraph 42.

In this instance, Member States should put in place a mechanism for calculation of costs that are to be assumed by the statutory social security system for such cross-border healthcare, provided that this mechanism is based on objective, non-discriminatory criteria known in advance and the costs assumed according to this mechanism are not less than what would have been assumed had the same or similar healthcare been provided in the territory of the Member State of affiliation.

## **7.2. Non-hospital care**

On the basis of the assessment of the current and future extent of cross-border non-hospital care as set out above, there is no evidence to suggest that such care will undermine either the financial sustainability of health and social security systems overall or the organisation, planning and delivery of health services<sup>26</sup>. On that basis, the obstacle to free movement represented by a prior authorisation requirement for such cross-border non-hospital care is not justified, and such prior authorisation should therefore not be required for non-hospital care.

However, Member States may have limitations on the choice of provider or other domestic planning mechanisms which are applied domestically, including conditions, criteria of eligibility and regulatory and administrative formalities. These may also be applied to cross-border non-hospital healthcare, provided they respect internal market freedoms and any such restrictions on access to non-hospital healthcare abroad are necessary, proportionate and non-discriminatory.

## **7.3. Hospital care**

As mentioned above, the Court of Justice in its judgements recognised the specific nature of health services provided by hospitals, for which planning is necessary<sup>27</sup>. However, there is no consistent definition of what constitutes hospital care throughout the different health systems of the EC. This diverse understanding gives rise to different interpretations in practice of the principles of free movement of health services established by the Court of Justice among the Member States. The difference of definition could therefore constitute on the one hand an obstacle to the freedom for patients to receive healthcare services because patients would be subject to different provisions within this directive depending on the definition of hospital care. In order to overcome that obstacle, it is necessary to provide a minimum Community definition of hospital care. The introduction of a minimum harmonized definition for the purposes of this directive will also ensure that there is no distortion of competition among health systems because they will all be subject to consistent rules.

The closest commonly-used definition to hospital care is that of inpatient care (meaning treatment that requires at least one night of stay in a hospital or clinic). For this reason, Article 8(1) introduces a minimum Community definition of hospital care on that basis. However, it may be appropriate to also consider as hospital care certain other kinds of treatment as hospital treatment, if that treatment requires use of highly specialised and cost-intensive medical infrastructure or medical equipment or involving treatments presenting a particular risk for the patient or the population

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<sup>26</sup> See in particular *Müller-Fauré and van Riet*, paragraph 93.

<sup>27</sup> See in particular *Smits and Peerbooms*, paragraphs 76-80.



Article 8(1) therefore also stipulates that a regularly updated technical list of such treatments may be specifically defined by the Commission.

As above mentioned and taking into account what the Court of Justice has held with regard to the free movement of services applied in the context of patients mobility, a system of prior authorisation for the reimbursement of hospital care provided in another Member State may be justified by the need to plan the number of hospital infrastructures, their geographical distribution, the mode of their organisation, the equipment with which they are provided and even the nature of the healthcare which they are able to offer. The aims of such planning is to ensure, within each Member State, access to a balanced range of quality hospital care, to secure efficient cost management and, so far as is possible, to avoid wastage of financial, technical or human resources<sup>28</sup>.

However, as with non-hospital care, on the basis of the assessment of the current and future extent of cross-border hospital care as set out above, there is no evidence to suggest that such care will undermine either the financial sustainability of health and social security systems overall or the organisation, planning and delivery of health services. Nevertheless, with regard to cross-border hospital care, it should be possible for Member States to introduce a system of prior authorisation to address situations where the financial balance of the health and social security system of a Member State, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on their national territory is seriously undermined or is likely to be seriously undermined. However, such systems of prior authorisation should be limited to cases where there is evidence that the outflow of patients due to cross-border hospital care undermines or is likely to undermine the financial sustainability of health and social security systems overall or the organisation, planning and delivery of health services. and that prior authorisation is necessary and proportionate to maintain the financial and organisational balance of the health and social security system in question. The prior authorisation system must be limited to what is necessary and proportionate to avoid such impact and shall not constitute a means of arbitrary discrimination.

In any event, as for non-hospital care, domestic limitations for planning reasons applied by Member States, including conditions, criteria of eligibility and regulatory and administrative formalities, may also be applied to cross-border hospital healthcare, provided they respect internal market freedoms and any such restrictions on access to hospital healthcare abroad are necessary, proportionate and non-discriminatory.

#### **7.4. Procedural guarantees**

According to established case-law, any national administrative procedures and decisions, that the access to cross-border provision of services is made subject to, are obstacles to the free movement of services unless they are objectively justified, necessary and proportionate. This is even more evident in the area of healthcare where administrative practices differ significantly between Member States, and often even between regions within Member States. It is therefore appropriate to require

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See again in particular *Smits and Peerbooms*, paragraphs 76-80.

that national administrative procedures regarding use of healthcare in another Member State provide to the patients comparable 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 these overall principles and the individual circumstances of each case. This should be the case regarding procedures relating to financial issues such as reimbursement (including reimbursement of costs of healthcare incurred in another Member State after the patient's return), but also medical procedures such as referral or seeking second opinions.

## **7.5. Information for patients and national contact points**

Appropriate information for patients is a necessary precondition for improving patients' confidence in cross-border healthcare and thus for achieving free movement of health services in the internal market as well as high level of health protection. The current practice in providing information to patients on aspects of cross-border healthcare in the Member States is rather limited. Many contributors to the consultation preceding these proposals felt that currently it is difficult for patients to identify their rights with regard to cross-border healthcare. Clear information is often felt to be missing. It was widely argued that in many Member States patients are not aware of the possibilities and their entitlement to receive treatment abroad and to get reimbursed. For example, a study conducted by the *Health Consumer Powerhouse* in France, Poland, United Kingdom, Spain and Germany showed that 25% of citizens believe that they do not have the right for treatment abroad and 30% are unsure<sup>29</sup>. As set out above, this was confirmed by the recent Eurobarometer survey<sup>30</sup> which showed that 30% of the citizens in the European Union are not aware of the possibility to receive healthcare outside their country of affiliation.

The directive therefore set outs the requirements for information on all essential aspects of cross-border healthcare to be provided to patients in order to achieve the objectives of the internal market. In order to improve provision of information to patients regarding cross-border healthcare, it is appropriate to require that such information is easily accessible and in particular, to establish national contact points for cross-border healthcare. The form as well as numbers of those national contact points is to be decided by the Member States. The national contact points can be also incorporated in or build on activities of existing information centres, provided that it is clearly indicated that they are also national contact points for cross-border healthcare. The national contact points should have appropriate facilities to provide information on possibilities for cross-border healthcare and the applicable processes, and to provide practical assistance to patients if needed. Such information about the process for having access to cross-border care (e.g.: procedures to be followed, timetable for reimbursement) is distinct from information about content of the healthcare itself (e.g.: cost, timetable for availability, outcomes), which should be provided by the providers in question and which is covered under Chapter II. The existence of national contact points does not preclude Member States from

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[http://ec.europa.eu/health/ph\\_overview/co\\_operation/mobility/docs/health\\_services\\_co147.pdf](http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/health_services_co147.pdf)  
Flash Eurobarometer Series #210, Cross-border health services in the EU, Analytical report, conducted by The Gallup Organization, Hungary upon the request of the European Commission, the Health and Consumer Protection Directorate-General (DG SANCO), 2007.

establishing other linked contact points at regional or local level, reflecting the specific organisation of their healthcare system.

## **7.6. Rules applicable to healthcare services**

When healthcare is received by a patient in a Member state, which is not the country 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 in case where healthcare providers temporarily move to another Member State to provide healthcare there or when healthcare is provided cross-border. Given that in accordance with the Treaty art.152.5 the organisation and delivery of health services and medical care rests upon Member States, the rules applicable to the actual provision of healthcare (as defined in Art.4 a) ) of the Directive has to be governed by the rules of the Member State of treatment. This indication in clear terms of this principle will help the patient in making an informed choice, and will avoid misapprehension and misunderstanding. It will also establish a high level of trust between the patient and the healthcare professional.

## **8. CHAPTER IV - COOPERATION ON HEALTHCARE**

### **8.1. Duty of cooperation**

Realising the potential of the internal market for cross-border healthcare requires cooperation between providers, purchasers and regulators of different Member States at national, regional or local level in order to ensure safe, high quality and efficient care across borders. In the patient mobility reflection process<sup>31</sup>, health ministers and other stakeholders identified areas where the economies of scale of coordinated action between all Member States can bring added value to national health systems. This may concern joint planning, mutual recognition or adaptation of procedures or standards, interoperability of respective national information and communication technology systems, practical mechanisms to ensure continuity of care or practical facilitating of cross-border provision of healthcare by health professionals on a temporary or occasional basis.

To achieve the objective of realising the potential of the internal market, this Directive requires the Member States to render mutual assistance necessary for achieving implementation of this Directive and to facilitate in cross-border healthcare provision at regional and local level. As the national, regional and local administrative practices in the healthcare sector differ significantly, mutual cooperation between different health systems will help to avoid unnecessary obstacles to the free movement of health services.

### **8.2. Recognition of prescriptions issued in another Member State**

Provision of medicinal products will often be part of cross-border healthcare, and may form part of an ongoing treatment protocol for a patient which should continue

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<sup>31</sup> For more information and the text of the report of the High Level Process of Reflection on patient mobility and healthcare developments in the European Union, see [http://europa.eu.int/comm/health/ph\\_overview/co\\_operation/mobility/patient\\_mobility\\_en.htm](http://europa.eu.int/comm/health/ph_overview/co_operation/mobility/patient_mobility_en.htm).

to be applied even if they move country. However, there are significant variations in the extent to which prescriptions issued in another country are accepted, which cause obstacles in practice to cross-border healthcare. Medicinal products licensed within the Community all have to meet harmonised standards of quality, safety and efficacy, and thus in principle it should be possible for prescriptions issued by an authorised person for a specific patient in one Member State to be dispensed in another, provided that the authenticity and content of the prescription are clear. In order to ensure a high level of health protection whilst also facilitating free movement of health services, specific measures should be put in place to verify the authenticity of the prescription and the authorised person who issued it, to ensure that the patient understands the information concerning the pharmaceutical product and (given variations in names and presentation between countries) to identify the medicinal product concerned, and certain categories of medicinal products should be excluded.

### **8.3. European reference networks and health technology assessment**

This Directive further provides for cooperation in the specific areas where the economies of scale of coordinated action between all Member States can bring significant added value to national health systems. This is the case for European reference networks (Article 15), which should provide healthcare to 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. Establishing European networking for such centres of reference would help to provide high-quality and cost-effective care as well as help to realise the potential of the internal market in this area by maximising the speed and scale of diffusion of innovations in medical science and health technologies, and would thus bring benefits of the internal market to both patients and healthcare systems as well as helping to promote the highest possible quality of care. The High Level Group on health services and medical care has already developed general conditions and criteria that European reference networks should fulfil, and these should be specified in detail through implementing measures taking into account the results of current pilot projects.

Similarly, this Directive provides for establishment of the Community network on health technology assessment (Article 17), which should support cooperation between responsible national authorities, support provision of objective, reliable, timely, transparent and transferable information on the short- and long-term effectiveness of health technologies, enable an effective exchange of this information within the network and to provide support to policy decisions by Member States. Currently there are wide variations and frequent duplication in such assessments between and within Member States in terms of the methodologies used and the consequent uptake of innovations, which act as a barrier to the free movement of the technologies concerned and (through the consequent variations in healthcare) undermine confidence in standards of safety and quality across the Union. Collaborating on providing common criteria with a view to establish such an evidence base at Community level will help to spread best practice, avoid duplication of resources and develop common core information packages and techniques that can then be used by Member States, to help them make best use of new technologies, therapies and techniques and as with European reference networks, will also help to

realise the potential of the internal market in this area by maximising the speed and scale of diffusion of innovations in medical science and health technologies.

#### **8.4. E-health**

Provision of cross-border healthcare does not necessarily require either the patient or the professional to physically change countries, but may be provided through information and communication technologies – this is the mode of supply referred to as 'cross-border provision of services', or "E-health". This is a mode of supply of growing importance, but one which presents specific challenges for ensuring that the different information and communication technologies of the health systems of the Member States are compatible (or "interoperable"). Widely different and incompatible formats and standards for information and communication technologies used in healthcare provision are used throughout the Community, creating both obstacles to this mode of cross-border healthcare provision and risks to health protection. It is therefore necessary to provide for Community harmonisation in this area in order to achieve the interoperability of Member States' information and communication technology. However, the proposal does not oblige any introduction of e-health systems or services but aims at ensuring interoperability once the choice of introducing such systems is done by Member States.

#### **8.5. Data collection**

Although the Commission (drawing on the extensive research and consultations preceding this proposal) has been able to estimate the likely extent and nature of cross-border healthcare, data on cross-border healthcare is not sufficiently available or comparable to enable long-term assessment and management of cross-border healthcare. Such data is vital to be able to monitor cross-border healthcare and its impact on health systems overall, in order to ensure that an appropriate balance is struck between free provision of health services, a high level of health protection and respecting the responsibilities of the Member States for ensuring the overall objectives of their health systems.

#### **8.6. Implementing committee**

Measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission. In particular, power should be conferred on the Commission to define for the purposes of this Directive a list of treatments, other than those requiring overnight accommodation, to be subject to the same regime as hospital care; accompanying measures to exclude specific categories of medicinal products or substances from the recognition of prescriptions issued in another Member State provided for in this Directive; a list of specific criteria and conditions that European reference networks must fulfil; 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, or to supplement this Directive by the addition of new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Proposal for a

**DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission<sup>32</sup>,

Having regard to the opinion of the European Economic and Social Committee<sup>33</sup>,

Having regard to the opinion of the Committee of the Regions<sup>34</sup>,

After consulting the European Data Protection Supervisor<sup>35</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty<sup>36</sup>,

Whereas:

- (1) According to 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 high level of human health protection has to be ensured also when the Community legislature acts under other Treaty provisions.
- (2) Given that that the conditions for recourse to Article 95 of the Treaty as a legal basis are fulfilled, the Community legislature 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, in achieving harmonisation, a high level of protection of human health should be guaranteed taking account in particular of any new development based on scientific facts.
- (3) 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 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 of Fundamental Rights of the European Union.<sup>37</sup> Specifically, this

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<sup>32</sup> OJ C [...], [...], p. [...].

<sup>33</sup> OJ C [...], [...], p. [...].

<sup>34</sup> OJ C [...], [...], p. [...].

<sup>35</sup> OJ C , , p. .

<sup>36</sup> OJ C [...], [...], p. [...].

<sup>37</sup> OJ C 364, 18.12.2000, p. 1.

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.

- (4) 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.<sup>38</sup> They are also part of the wider framework of services of general interest.
- (5) As confirmed by the Court of Justice on several occasions, while recognizing their specific nature, all types of medical care fall within the scope of the Treaty.
- (6) Some issues related to cross-border healthcare, in particular reimbursement of healthcare provided in a Member State other than that in which the recipient of the care is resident, have been already addressed by the Court of Justice. As healthcare was excluded from the scope of Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market<sup>39</sup> 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.
- (7) In its Conclusions of 1-2 June 2006<sup>40</sup>, the Council of the European Union has adopted a statement on "Common values and principles in European Union health systems" and recognised particular value of an initiative on cross-border healthcare ensuring clarity for European citizens about their rights and entitlements when they move from one Member State to another in order to ensure legal certainty.
- (8) This directive aims to establish a general framework for provision of safe, high quality and efficient cross-border healthcare in the Community and to ensure patients mobility and freedom to provide healthcare and 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 the organisation and delivery of healthcare and medical care and social security benefits in particular for sickness.
- (9) 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 their special nature nor the way in which they are organised or financed removes them from the ambit of the fundamental principle of freedom of movement. As regards long-term care, the Directive does not apply to assistance and support for families or individuals who are, over an extended period of time, in a particular state of need. It 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.

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<sup>38</sup> Council Conclusions on Common values and principles in European Union Health Systems, OJ C 146, 22.6.2006, p.1.

<sup>39</sup> OJ L 376, 27.12.2006, p.36.

<sup>40</sup> OJ C 146, 22.6.2006, p.1.

- (10) For the purpose of this Directive, the concept of "cross-border healthcare" covers the following modes of supply of healthcare:
- Use of healthcare abroad (i.e.: a patient moving to a healthcare provider in another Member State for treatment); this is what is referred to as 'patient mobility';
  - Cross-border provision of healthcare (i.e.: delivery of service from the territory of one Member State into the territory of another); such as telemedicine services, remote diagnosis and prescription, laboratory services;
  - Permanent presence of a healthcare provider (i.e.: establishment of a healthcare provider in another Member State); and,
  - Temporary presence of persons (i.e.: mobility of health professionals, for example moving temporarily to the Member State of the patient to provide services).
- (11) As recognised by the Member States in the Council Conclusions on Common values and principles in European Union Health Systems<sup>41</sup> there is a set of operating principles that are shared by health systems throughout the Community. These 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 these shared 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, who 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 and free movement of provision of healthcare in the internal market as well as a high level of health protection.
- (12) 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 that the requirements to ensure that healthcare is provided according to common principles and clear quality and safety standards are applicable to all type of healthcare in order to ensure the freedom to provide and obtain cross border 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 within the internal market, non-discrimination inter alia with regard to nationality (or in the case of legal persons, with regard to the Member State in which they are established), necessity and proportionality of any restrictions on free movement. However, nothing in this Directive requires healthcare providers to accept for planned treatment or to

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<sup>41</sup> OJ C 146, 22.6.2006, p. 1.



prioritise patients from other Member States to the detriment of other patients with similar health needs, such as through increasing waiting time for treatment.

- (13) 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 recognized in Art.21 of the Charter they should in no way be discriminated upon 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 of Fundamental Rights of the European Union, it has to be implemented and applied with due respect for the rights 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 Directive 2000/43/EC of the Council of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin, and other Directives giving effect to Article 13 of the EC Treaty. In the light of this, the 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.
- (14) In any event, any measure taken by Member States with a view to ensure that healthcare is provided according to clear quality and safety standards, should not constitute new barriers to the free movement of health professionals as enshrined by 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<sup>42</sup>.
- (15) Research suggests that harm arises from healthcare in around 10% of cases. Ensuring clear common obligations to deal with circumstances of responding to harm arising from healthcare 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 country of treatment should be without prejudice to the possibility for Member States to extend the coverage of their domestic systems to patients from their country seeking healthcare abroad, where this is more appropriate to the patient, in particular in the case of patients for whom use of healthcare in another Member State is necessary.
- (16) Member States should ensure, that mechanisms for the protection of patients and the 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.

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<sup>42</sup> OJ L 255, 30.9.2005, p. 22. Directive as last amended by Council Directive 2006/100/EC (OJ L 363, 20.12.2006, p.141)

- (17) The right to the protection of personal data is a fundamental right recognised by Article 8 of the Charter of Fundamental Rights of the European Union.<sup>43</sup> Ensuring continuity of cross-border healthcare depends on transfer of personal data concerning patient's health. These personal data should be able to flow freely from one Member State to another, but in the same time the fundamental rights of the individuals should be safeguarded. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data<sup>44</sup> 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.
- (18) The right to reimbursement of the costs of healthcare provided in another Member State from the statutory social security scheme of patients as insured persons was recognised by the Court of Justice in several judgements. The Court of Justice has held that the Treaty provisions on the freedom to provide services includes the freedom for the recipients of healthcare, including persons in need of medical treatment, to go to another Member State in order to receive it there. The same applies to recipients of healthcare seeking to receive healthcare provided in another Member State through other means, for example through e-health services. Whilst Community law does not detract from the power of the Member States to organise their healthcare and social security systems, Member States must when exercising that power comply with Community law, in particular with the Treaty provisions on the freedom to provide services. Those provisions prohibit the Member States from introducing or maintaining unjustified restrictions on the exercise of that freedom in the healthcare sector.
- (19) 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.
- (20) 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 patient's rights to be granted an authorisation for a 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 (EC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community<sup>45</sup> and Article 20 of Council Regulation (EC) No 883/2004 of the European

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<sup>43</sup> OJ C 364, 18.12.2000, p. 1.

<sup>44</sup> OJ L 281, 23.11.1995, p.31.

<sup>45</sup> OJ L 149, 5.7.1971, p.2. Regulation as last amended by Regulation (EC) No 1992/2006, (OJ L 392, 30.12.2006, p. 1).

Parliament and of the Council of 29 April 2004 on the coordination of social security systems<sup>46</sup> are met.

- (21) It is appropriate to require that also patients who go for healthcare to another Member State in other circumstances than those envisaged for coordination of social security schemes established by the Regulation (EC) No. 1408/71 should be able to benefit from the principles of free movement of services in accordance with the Treaty and the provisions of this Directive. Patients should be guaranteed assumption of the costs of that healthcare at least at the level provided for the same or similar healthcare had they been provided in the Member State of affiliation. This fully respects responsibility of the Member States to determine the extent of the sickness cover available to their citizens and prevents any significant effect on the financing of the national healthcare systems. 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 as mentioned in Article 15 of this Directive.
- (22) For the patient, therefore, the two systems are coherent; either this directive applies or Regulation 1408/71. In any event, any insured person who requests an authorisation to receive a treatment appropriate to his/her condition in another Member State shall always be granted this authorisation under the conditions provided for in Regulation 1408/71 and 883/04 when the treatment in question cannot be given within the time medically justifiable, taking account his current state of health and the probable course of the disease. The patient should not be deprived of the more beneficial rights guaranteed by Regulation.1408/71 and 883/04 when the conditions are met.
- (23) The patient may choose which mechanism they prefer, but in any case, where the application of Regulation 1408/71 is more beneficial for the patient, the patient should not be deprived of the rights guaranteed by that Regulation.
- (24) The patient should, in any event, not derive a financial advantage from the healthcare provided in another Member State and the assumption of costs should be therefore limited only to actual costs of healthcare received.
- (25) This Directive does not aim either to create entitlement for reimbursement of treatment in another Member State, if such a treatment is 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 provided in another Member State according to its provisions.
- (26) 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 the Directive fully respects the differences of national health-care

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<sup>46</sup> OJ L 166, 30.4.2004, p. 1.

systems and the Member States' responsibilities for organisation and delivery of health services and medical care.

- (27) This Directive provides also for the right for a patient to receive any medicinal product authorised for marketing in the Member State where healthcare is provided, even if the medicinal product is not authorised for marketing in the Member State of affiliation, as it is an indispensable part of obtaining effective treatment in another Member State.
- (28) Member States may maintain general conditions, criteria for eligibility and regulatory and administrative formalities for receipt of healthcare and reimbursement of healthcare costs, such as the requirement to consult a general practitioner before consulting a specialist or before receiving hospital care, also in relation to patients seeking healthcare in another Member State provided that such conditions are necessary, proportionate to the aim and are not discretionary and discriminatory. It is thus appropriate to require that these general conditions and formalities are being applied in an objective, transparent and non-discriminatory way and are known in advance, 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 in comparison with patients being treated in their Member State of affiliation, and that decisions are made as quickly as possible. This is without prejudice to the rights of the Member States to provide for criteria or conditions of prior authorisation in the case of patients seeking healthcare in their Member State of affiliation.
- (29) Any healthcare which is not regarded as hospital care according to 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.
- (30) 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 appropriate to submit to the same regime of hospital care also 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 for the patient or the population (e.g. treatment of serious infectious diseases). A regularly updated list of such treatments shall be specifically defined by the Commission through the comitology procedure.
- (31) 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 this 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 concerned Member. As the assessment of the precise impact of an expected outflow of patients requires complex assumptions and calculations, the 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.

- (32) 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 States in accordance with the provision of this Directive, the costs of such care provided in another Member State should also be reimbursed by the Member State of affiliation up to the level of costs that would have been assumed had the same or similar healthcare been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received. However, when the conditions set out in Article 22(2) of Regulation (EC) 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 shall not apply. This is in line with the case law of the Court of Justice which has specified that patients who received a refusal of authorisation subsequently held to be unfounded, are entitled to have the cost of the treatment obtained in another Member State reimbursed in full according to the provisions of the legislation in the Member State of treatment.
- (33) 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 of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications should not be affected by these general rules.

- (34) 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, these central contact points should also constitute a network through which such questions can be most efficiently addressed. These 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.
- (35) When healthcare is received by a patient in a Member state, which is not the country 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 in case where healthcare providers temporarily move to another Member State to provide their medical services there or when healthcare is provided cross-border. 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 Art.5, given that in accordance with Art. 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 in making an informed choice, and will avoid misapprehension and misunderstanding. It will also establish a high level of trust between the patient and the healthcare provider
- (36) The Member States should decide on the form of those national contact points as well as the number of them. The national contact points may be also incorporated in or build on activities of existing information centres provided that it is clearly indicated that they are also national contact points for cross-border healthcare. The national contact points should have appropriate facilities to provide information on the main aspects of cross-border healthcare and to provide practical assistance to patients if needed. The Commission should work together with the Member States in order to facilitate cooperation regarding national contact points for cross-border healthcare, including making relevant information available at Community level, such as through the European Health Portal. 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.
- (37) Realising the potential of the internal market for cross-border healthcare requires cooperation between providers, purchasers and regulators of different Member States at national, regional or local level in order to ensure safe, high quality and efficient care across borders. This is particularly the case for cooperation in border regions, where cross-border provision of services may be the most efficient way of organising health services for the local populations, but where achieving such cross-border provision on a sustained basis requires cooperation between the health systems of different Member States. Such cooperation may concern joint planning, mutual

recognition or adaptation of procedures or standards, interoperability of respective national information and communication technology systems, practical mechanisms to ensure continuity of care or practical facilitating of cross-border provision of healthcare by health professionals on a temporary or occasional basis. Directive 2005/36/EC on the recognition of professional qualifications stipulates that free provision of services of a temporary or occasional nature, including services provided by health professionals, in another Member State should not, subject to specific provisions of Community law, be restricted for any reason relating to professional qualifications. This Directive should be without prejudice to those provisions of Directive 2005/36/EC.

- (38) 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).
- (39) Where medicinal products are authorised within the patient's Member State 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<sup>47</sup> and have been prescribed in another Member State for an individual named patient, it should be in principle possible for such prescriptions to be medically recognised 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. 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.
- (40) 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 to organise at European level equal access to high level shared expertise in a given medical field for all patients as well as for health professionals.
- (41) 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

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<sup>47</sup> OJ L 311, 28.11.2001, p. 67. Directive as last amended by Regulation (EC) No 1901/2006 of the European Parliament and of the Council (OJ L 378, 27.12.2006, p. 1).

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 through 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.

- (42) 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 so 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 .../...of the European Parliament and of the Council on Community statistics on public health and health and safety at work [COM(2007)46], the health information system established within the framework of the health programme established by the 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)<sup>48</sup> 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<sup>49</sup>.
- (43) The constant progress of medical science and health technologies presents both opportunities and challenges to the health systems of the Member States. Cooperation in the evaluation of new health technologies can support Member States through economies of scale and avoiding duplication of effort, and provide a better basis of evidence for optimal use of new technologies to ensure safe, high-quality and efficient healthcare. This will also contribute to the internal market by maximising the speed and scale of diffusion of innovations in medical science and health technologies. Such cooperation requires sustained structures involving all the relevant authorities of all the Member States, building on existing pilot projects.
- (44) 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<sup>50</sup>.
- (45) In particular, power should be conferred on the Commission to adopt the following measures: a list of treatments, other than those requiring overnight accommodation, to be subject to the same regime as hospital care; accompanying measures to exclude specific categories of medicinal products or substances from the recognition of prescriptions issued in another Member State provided for in this Directive; a list of specific criteria and conditions that European reference networks must fulfil; the procedure for establishing European reference networks. Since those measures are of

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<sup>48</sup> OJ L L 271, 9.10.2002, p. 1.

<sup>49</sup> OJ L 142, 30.4. 2004, p.1.

<sup>50</sup> OJ L 184, 17.7.1999, p.23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p.11).



general scope and are designed to amend non-essential elements of this Directive, or to supplement this Directive by the addition of new non-essential elements, they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

- (46) Since the objectives of this Directive, namely establishing of 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 those objectives.

HAVE ADOPTED THIS DIRECTIVE:

## **CHAPTER I**

### **GENERAL PROVISIONS**

#### *Article 1*

##### **Aim**

This Directive establishes a general framework for the provision of safe, high quality and efficient cross-border healthcare.

#### *Article 2*

##### **Scope**

This Directive shall apply to provision of healthcare regardless of how it is organised, delivered and financed or whether it is public or private.

#### *Article 3*

##### **Relationship with other Community provisions**

1. This Directive shall apply without prejudice to:
  - (a) 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 concerning the processing of personal data and the protection of privacy in the electronic communications sector<sup>51</sup>;

- (b) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency<sup>52</sup> and Directive 2001/83/EC on the Community code relating to medicinal products for human use;
- (c) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use<sup>53</sup>;
- (d) Directive 96/71/EC of the European Parliament and of the Council of 16 December 1996 concerning the posting of workers in the framework of the provision of services<sup>54</sup>.
- (e) Directive 2000/43/EC of the Council of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin.
- (f) Regulations on coordination of social security schemes, in particular Article 22 of Regulation (EC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community<sup>55</sup> and Council Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems<sup>56</sup>.
- (g) Regulation (EC) 1082/2006 of 5 July 2006 on a European Grouping of territorial cooperation (EGTC)<sup>57</sup>

2. When the circumstances under which an authorisation to go to another Member State in order to receive appropriate treatment under Article 22 of Regulation (EC) No 1408/71 must be granted are met, the provisions of that Regulation shall apply and the provisions of Articles 6, 7, 8 and 9 of this Directive shall not apply. Conversely, when an insured person seeks healthcare in another Member State in other circumstances, Articles 6, 7, 8 and 9 of this Directive apply and Article 22 of Council Regulation (EC) No 1408/71 shall not apply. However, whenever the conditions for granting an authorisation set out in Article 22(2) of Regulation (EC) No 1408/71 are fulfilled, the authorisation shall be accorded and the benefits provided in accordance

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<sup>51</sup> OJ L 201, 31.7.2002, p. 37. Directive as last amended by Directive 2006/24/EC (OJ L 105, 13.4.2006, p.54).

<sup>52</sup> OJ L 136, 30.4.2004, p.1. Regulation as amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p. 1).

<sup>53</sup> OJ L 121, 1.5.2001, p.34.

<sup>54</sup> OJ L 18, 21.1.1997, p. 1.

<sup>55</sup> OJ L 149, 5.7.1971, p.2. Regulation as last amended by Regulation (EC) No 1992/2006, (OJ L 392, 30.12.2006, p. 1).

<sup>56</sup> OJ L 166, 30.4.2004, p. 1.

<sup>57</sup> OJ L 210, 31.7.2006, p. 19.

with that Regulation. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply.

3. If the provisions of this Directive conflict with a provision of another Community act governing specific aspects of healthcare, the provision of the other Community act shall prevail and shall apply to those specific situations concerned. These include:
  - (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<sup>58</sup>.
4. Member States shall apply the provisions of this Directive in compliance with the rules of the EC Treaty.

#### *Article 4*

### **Definitions**

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

- (a) "healthcare" means a health service provided by or under the supervision of a health professional in exercise of his profession, and regardless of the ways in which it is organised, delivered and financed at national level or whether it is public or private;
- (b) "cross-border healthcare" means healthcare provided in a Member State other than that where the patient is an insured person or healthcare provided in a Member State other than that where the healthcare provider resides, is registered or is established;
- (c) "use of healthcare in another Member State" means healthcare provided in the Member State other than that where the patient is an insured person;
- (d) "health professional" means a doctor of medicine or a nurse responsible for general care or a dental practitioner or a midwife or a pharmacist within the meaning of Directive 2005/36/EC or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC;
- (e) "healthcare provider" means any natural 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:

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<sup>58</sup> OJ L 178, 17.7.2000, p. 1.

- (i) until the date of application of Regulation (EC) No 883/2004: a person who is insured in accordance with the provisions of Articles 1, 2 and 4 of Regulation (EC) No 1408/71,
- (ii) as from the date of application of Regulation (EC) No 883/2004: a person who is an insured person within the meaning of Article 1(c) of Regulation (EC) No 883/2004;
- (h) "Member State of affiliation" means the Member State where the patient is an insured person;
- (i) "Member State of treatment" means the Member State on whose territory cross-border healthcare is actually provided;
- (j) "medicinal product" means a medicinal product as defined by Directive 2001/83/EC;
- (k) "prescription" means a medicinal prescription as defined by the Directive 2001/83/EC including prescriptions issued and transmitted electronically (ePrescriptions);
- (l) "harm" means adverse outcomes or injuries stemming from the provision of healthcare.

## **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 and safety standards for healthcare provided on their territory, and ensure that:
  - (a) mechanisms are in place for ensuring that healthcare providers are able to meet such standards, taking into account international medical science and generally recognised good medical practices;
  - (b) the application of such standards by healthcare providers in practice is regularly monitored and corrective action is taken when appropriate standards are not met, taking into account progress in medical science and health technology;

- (c) healthcare providers provide all relevant information to enable patients to make an informed choice, in particular on availability, prices and outcomes of the healthcare provided and details of their insurance cover or other means of personal or collective protection with regard to professional liability;
  - (d) patients have a means of making complaints and are guaranteed remedies and compensation when they suffer harm arising from the healthcare they receive;
  - (e) systems of professional liability insurance or a guarantee or similar arrangement, which are equivalent or essentially comparable as regards their purpose and which are appropriate to the nature and the extent of the risk are in place for treatment provided on their territory;
  - (f) 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;
  - (g) patients from other Member States shall enjoy equal treatment with the nationals of the Member State of treatment, including the protection against discrimination provided for according to Community law and national legislation in force in the Member State of treatment.
2. Any measures taken by Member States, when implementing this Article, shall respect the provisions of Directive 2005/36/EC on the recognition of professional qualifications and Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce.
  3. 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, shall develop guidelines to facilitate the implementation of paragraph 1.

## **CHAPTER III**

### **USE OF HEALTHCARE IN ANOTHER MEMBER STATE**

#### *Article 6*

##### **Healthcare provided in another Member State**

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 of the Member State of affiliation to which the insured person is entitled. The Member State of affiliation shall

reimburse the costs to the insured person, which would have been paid for by its statutory social security system had the same or similar healthcare been provided in its territory. 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.

2. The costs of healthcare provided in another Member State shall be reimbursed 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 had the same or similar healthcare been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received.
3. 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 for receiving healthcare and reimbursement of healthcare costs as it would impose if the same or similar healthcare was provided in its territory, in so far as they are neither discriminatory nor an obstacle to freedom of movement of persons.
4. Member States shall have a mechanism for calculation of costs that are to be reimbursed to the insured person by the statutory social security 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 according to this mechanism shall be not less than what would have been assumed had the same or similar healthcare been provided in the territory of the Member State of affiliation.
5. Patients travelling to another Member State with the purpose of receiving healthcare there 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.

#### *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 subject to prior authorisation, where the cost of that care, if it had been provided in its territory, would have been paid for by its social security system.

#### *Article 8*

### **Hospital and specialised care**

1. For the purposes of reimbursement of healthcare provided in another Member State in accordance with this Directive, hospital care shall mean:

- (a) healthcare which requires overnight accommodation of the patient in question for at least one night.
- (b) healthcare, included in a specific list, that does not require overnight accommodation of the patient for at least one night. This list shall be limited to:
- healthcare that requires use of highly specialised and cost-intensive medical infrastructure or medical equipment; or
  - healthcare involving treatments presenting a particular risk for the patient or the population.
2. This list shall be set up and may be regularly updated by the Commission. Those measures, 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 19(3).
3. 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 in its territory, it would have been assumed by the Member State's social security system; and
  - (b) the purpose of the system is to address the consequent outflow of patients due to the implementation of the present Article and to prevent it from seriously undermining, or being likely to seriously 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.
4. The prior authorisation system shall be limited to what is necessary and proportionate to avoid such impact, and shall not constitute a means of arbitrary discrimination.
5. The Member State shall make publicly available all relevant information on the prior authorisation systems introduced pursuant to the provisions of paragraph 3.

#### *Article 9*

#### **Procedural guarantees regarding the use of healthcare in another Member State**

1. The Member State of affiliation shall ensure that administrative procedures regarding the use of healthcare in another Member State related to any prior authorisation referred to in Article 8(3), reimbursement of costs of healthcare incurred in another Member State and other conditions and formalities referred to in Article 6(3), 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 Art. 3.1 f) whenever the conditions of Art.22.1 c) and Art. 22.2 of Regulation 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 time limits set out and made public in advance by the Member States.
3. Member States shall specify in advance and in a transparent way the criteria for refusal of the prior authorisation referred to in Article 8(3).
4. Member States shall, when setting out the time limits within which requests for the use of healthcare in another Member State must be dealt with, take into account:
  - (a) the specific medical condition,
  - (b) the patient's degree of pain,
  - (c) the nature of the patient's disability, and
  - (d) the patient's ability to carry out a professional activity.
5. Member States shall ensure that any administrative decisions regarding the use of healthcare in another Member State are subject to administrative review and also capable of being challenged in judicial proceedings, which include provision for interim measures.

#### *Article 10*

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

1. The Member States of affiliation shall ensure that there are mechanisms in place to provide patients on request with information on receiving healthcare in another Member State, and the terms and conditions that would apply, inter alia, whenever harm is caused as a result of healthcare received in another Member State.
2. The information referred to in paragraph 1 shall be made easily accessible, including by electronic means, 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.
3. The Commission may, in accordance with the procedure referred to in Article 19(2), develop a standard Community format for the prior information referred to in paragraph 1.



## *Article 11*

### **Applicable rules 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, or in a Member State other than that where the healthcare provider resides, is registered or established, such healthcare service is provided according to the legislation of the Member State of treatment in accordance with Art.5.
2. This article does not apply as far as the recognition of the professional qualifications is concerned.

## *Article 12*

### **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.
2. The national contact point in the Member State of affiliation shall, in close cooperation with other competent national authorities, and with national contact points in other Member States, in particular in the Member State of treatment, and with the Commission:
  - (a) provide and disseminate information to patients in particular on their rights related to cross-border healthcare and the guarantees of quality and safety, protection of personal data, procedures for complaints and means of redress available for healthcare provided in another Member State, and on the terms and conditions applicable;
  - (b) 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; the national contact point shall in particular inform patients about the options available to settle any dispute, help to identify the appropriate out-of-court settlement scheme for the specific case and help patients to monitor their dispute where necessary;
  - (c) gather detailed information on national bodies operating out-of-court settlement of disputes and facilitate co-operation with those bodies;
  - (d) facilitate the development of international out-of-court settlement scheme for disputes arising from cross-border healthcare;
3. The Commission shall, in accordance with the procedure referred to in Article 19(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 paragraph 2(a) of this Article.

## **CHAPTER IV**

### **COOPERATION ON HEALTHCARE**

#### *Article 13*

##### **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.

#### *Article 14*

##### **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 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.
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 through developing a Community prescription template, and supporting interoperability of ePrescriptions;
  - (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;

- (c) measures to exclude specific categories of medicinal products from the recognition of prescriptions provided for under this article where necessary in order to safeguard public health.
- 3. The measures referred to in points (a) and (b) of paragraph 2 shall be adopted in accordance with the regulatory procedure referred to in Article 19(2). The measures referred to in point (c) of paragraph 2, 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 19(3).
- 4. 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 15*

### **European reference networks**

- 1. Member States shall facilitate the development of the European reference networks of healthcare providers. Those networks shall at all times be open for 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 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.
  - (c) to maximise cost-effective use of resources by concentrating them where appropriate;
  - (d) to help to share knowledge and provide training for health professionals;
  - (e) to provide quality and safety benchmarks and to help develop and spread best practice within and outside the network;
  - (f) 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.
- 3. The Commission shall adopt:
  - (a) a list of specific criteria and conditions that the European reference networks must fulfil, including 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.
- (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 19(3).

### *Article 16*

### **E-health**

The Commission shall, in accordance with the procedure referred to in Article 19(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 reflect developments in health technologies and medical science and respect the fundamental right to the protection of personal data in accordance with the applicable law. 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.

## *Article 17*

### **Cooperation on management of new health technologies**

1. Member States shall facilitate development and functioning of a network connecting the national authorities or bodies responsible for 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 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.
3. Member States shall designate the authorities or bodies participating in the network as referred to in paragraph 1 and communicate to the Commission names and contact details of those authorities or bodies.
4. The Commission shall, in accordance with the procedure referred to in Article 19(2), adopt the necessary measures for the establishment and the management of this network and specifying the nature and type of the information to be exchanged.

## *Article 18*

### **Data collection for statistical and monitoring purposes**

1. Member States shall collect statistical and other additional 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.
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 .../...of the European Parliament and of the Council on Community statistics on public health and health and safety at work [COM(2007)46], the Commission shall, in accordance with the procedure referred to in Article 19(2), adopt measures for the implementation of this Article.

## **CHAPTER V**

### **IMPLEMENTING AND FINAL PROVISIONS**

#### *Article 19*

##### **Committee**

1. The Commission shall be assisted by a Committee, consisting of representatives of the Member States and chaired by the Commission representative.
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 of that Decision. The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 3 months.
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 20*

##### **Reports**

The Commission shall within five years after the date referred to in Article 22(1) draw up a report on the operation of this Directive and submit it to the European Parliament and to the Council.

To that end and without prejudice to Article 22, the Member States shall communicate to the Commission any measure they have introduced, modified or maintained with a view to implement the procedures laid down in Articles 8 and 9.

#### *Article 21*

##### **References to other legislation**

As from the date of applicability of Regulation (EC) No. 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security schemes<sup>59</sup> :

- references to Council Regulation 1408/71/EC in this Directive shall be construed as references to Regulation 883/2004;

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<sup>59</sup> OJ L 166, 30.4.2004, p.1.

- references to Article 22 of Council Regulation 1408/71/EC in this Directive shall be construed as references to Article 20 of Regulation 883/2004.

## *Article 22*

### **Transposition**

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by ... [one year after its entry into force].

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 23*

### **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 24*

### **Addressees**

This Directive is addressed to the Member States.

Done at Brussels, [...]

*For the European Parliament*  
*The President*  
[...]

*For the Council*  
*The President*  
[...]

## LEGISLATIVE FINANCIAL STATEMENT

### 1. NAME OF THE PROPOSAL:

Proposal for a Directive of the European Parliament and of the Council for the application of cross-border healthcare patient rights

### 2. ABM / ABB FRAMEWORK

Public health

### 3. BUDGET LINES

#### 3.1. Budget lines (operational lines and related technical and administrative assistance lines (ex- B.A lines)) including headings:

XX0101: for the payment of the officials

XX010211: for the payment of the committee costs

#### 3.2. Duration of the action and of the financial impact:

From 2009, duration not defined

This budget intends to cover the costs of the future Committee on cross-border healthcare that will be set up as announced in the Directive after the adoption of that Directive by the Parliament and the Council:

2 FTE administrator valued at €117,000 each (according to the specific Guidelines), to support the comitology process.

Costs of the plenary session, with one participant from the 27 Member States. 10 meetings scheduled per year, valued at €20,000 each. Actual costs of the meetings and frequency of those meetings might need revision, depending on the final shape of the directive, after adoption by council and parliament, and the necessary comitology structures.

#### 3.3. Budgetary characteristics:

Budget line	Type of expenditure		New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective
XX 0101	Comp	Non-diff <sup>60</sup>	NO	NO	NO	5
XX 010211	Non com	Non-diff <sup>61</sup>	NO	NO	NO	5

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<sup>60</sup> Non-differentiated appropriations hereafter referred to as NDA

<sup>61</sup> Non-differentiated appropriations hereafter referred to as NDA



## 4. SUMMARY OF RESOURCES

### 4.1. Financial Resources

#### 4.1.1. Summary of commitment appropriations (CA) and payment appropriations (PA)

EUR million (to 3 decimal places)

Expenditure type	Section no.		2009	n + 1	n + 2	n + 3	n + 4	n + 5 and later	Total
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#### Operational expenditure<sup>62</sup>

Commitment Appropriations (CA)	8.1.	a							
Payment Appropriations (PA)		b							

#### Administrative expenditure within reference amount<sup>63</sup>

Technical & administrative assistance (NDA)	8.2.4.	c							
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#### TOTAL REFERENCE AMOUNT

Commitment Appropriations		a+c							
Payment Appropriations		b+c							

#### Administrative expenditure not included in reference amount<sup>64</sup>

Human resources and associated expenditure (NDA)	8.2.5.	d	0.234	0.234	0.234	0.234	0.234	0.234	1.404
Administrative costs, other than human resources and associated costs, not included in reference amount (NDA)	8.2.6.	e	0.200	0.200	0.200	0.200	0.200	0.200	1.200

#### Total indicative financial cost of intervention

TOTAL CA including cost of Human Resources		a+c+d+e	0.234	0.234	0.234	0.234	0.234	0.234	1.404
TOTAL PA including cost of Human Resources		b+c+d+e	0.200	0.200	0.200	0.200	0.200	0.200	1.200

<sup>62</sup> Expenditure that does not fall under Chapter xx 01 of the Title xx concerned.

<sup>63</sup> Expenditure within article xx 01 04 of Title xx.

<sup>64</sup> Expenditure within chapter xx 01 other than articles xx 01 04 or xx 01 05.

### Co-financing details: not applicable

If the proposal involves co-financing by Member States, or other bodies (please specify which), an estimate of the level of this co-financing should be indicated in the table below (additional lines may be added if different bodies are foreseen for the provision of the co-financing):

EUR million (to 3 decimal places)

Co-financing body		Year n	n + 1	n + 2	n + 3	n + 4	n + 5 and later	Total
.....	f							
TOTAL CA including co-financing	a+c +d+ e+f							

#### 4.1.2. Compatibility with Financial Programming

- ☒ Proposal is compatible with existing financial programming.
- ☐ Proposal will entail reprogramming of the relevant heading in the financial perspective.
- ☐ Proposal may require application of the provisions of the Interinstitutional Agreement<sup>65</sup> (i.e. flexibility instrument or revision of the financial perspective).

#### 4.1.3. Financial impact on Revenue

- ☒ Proposal has no financial implications on revenue
- ☐ Proposal has financial impact – the effect on revenue is as follows:

EUR million (to one decimal place)

		Prior to action [Year n- 1]	Situation following action					
Budget line	Revenue		[Year n]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5] <sup>66</sup>
	a) Revenue in absolute terms							
	b) Change in revenue	Δ						

<sup>65</sup> See points 19 and 24 of the Interinstitutional agreement.

<sup>66</sup> Additional columns should be added if necessary i.e. if the duration of the action exceeds 6 years

**4.2. Human Resources FTE (including officials, temporary and external staff) – see detail under point 8.2.1.**

Annual requirements	Year n	n + 1	n + 2	n + 3	n + 4	n + 5 and later
Total number of human resources	2	2	2	2	2	2

**5. CHARACTERISTICS AND OBJECTIVES**

**5.1. Need to be met in the short or long term**

Not applicable.

**5.2. Value-added of Community involvement and coherence of the proposal with other financial instruments and possible synergy**

Not applicable.

**5.3. Objectives, expected results and related indicators of the proposal in the context of the ABM framework**

Not applicable.

**5.4. Method of Implementation (indicative)**

☐ ***Centralised Management***

☒ directly by the Commission

☐ indirectly by delegation to:

☐ executive Agencies

☐ bodies set up by the Communities as referred to in art. 185 of the Financial Regulation

☐ national public-sector bodies/bodies with public-service mission

☐ ***Shared or decentralised management***

☐ with Member states

☐ with Third countries

☐ ***Joint management with international organisations (please specify)***

Relevant comments:

## **6. MONITORING AND EVALUATION**

### **6.1. Monitoring system**

Regular reporting of the working groups will be ensured and disseminated to the member States and Commission services.

### **6.2. Evaluation**

#### *6.2.1. Ex-ante evaluation*

Not applicable.

#### *6.2.2. Measures taken following an intermediate/ex-post evaluation (lessons learned from similar experiences in the past)*

Not applicable.

#### *6.2.3. Terms and frequency of future evaluation*

An evaluation of the running of the working group will be done after 5 years.

## **7. ANTI-FRAUD MEASURES**

Not applicable.

## 8. DETAILS OF RESOURCES

### 8.1. Objectives of the proposal in terms of their financial cost

Commitment appropriations in EUR million (to 3 decimal places)

(Headings of Objectives, actions and outputs should be provided)	Type of output	Av. cost	Year n		Year n+1		Year n+2		Year n+3		Year n+4		Year n+5 and later		TOTAL	
			No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost
OPERATIONAL OBJECTIVE No.1 <sup>67</sup> .....																
Action 1: Committee on cross-border healthcare																
- - Output	N° meetings		10	0.200	10	0.200	10	0.200	10	0.200	10	0.200	10	0.200	60	1.200
- Output 2																
Action 2.....																
- Output 1																
Sub-total Objective 1																
OPERATIONAL OBJECTIVE No.2 <sup>1</sup> .....																

<sup>67</sup>

As described under Section 5.3

<b>Action 1.....</b>																
- Output 1																
Sub-total Objective 2																
<b>OPERATIONAL OBJECTIVE No.n 1</b>																
Sub-total Objective n																
<b>TOTAL COST</b>																

## 8.2. Administrative Expenditure

### 8.2.1. Number and type of human resources

Types of post		Staff to be assigned to management of the action using existing and/or additional resources ( <b>number of posts/FTEs</b> )					
		Year n	Year n+1	Year n+2	Year n+3	Year n+4	Year n+5
Officials or temporary staff <sup>68</sup> (XX 01 01)	A*/AD	2	2	2	2	2	2
	B*, C*/AST						
Staff financed <sup>69</sup> by art. XX 01 02							
Other staff <sup>70</sup> financed by art. XX 01 04/05							
<b>TOTAL</b>							

### 8.2.2. Description of tasks deriving from the action

Running of the new comitology Committee ("Committee on safe, high-quality and efficient cross-border healthcare") established in accordance with Article 19 of this Directive and its working groups that will work on the implementation of the Directive

Costs of the plenary session, with one participant from the 27 Member States. 10 meetings scheduled per year, valued at €20,000 each. Actual costs of the meetings and frequency of those meetings might need revision, depending on the final shape of the directive, after adoption by the Council and the Parliament.

The needs for human and administrative resources shall be covered within the allocation granted to the managing DG in the framework of the annual allocation procedure.

### 8.2.3. Sources of human resources (statutory)

- ☒ Posts currently allocated to the management of the programme to be replaced or extended
- ☐ Posts pre-allocated within the APS/PDB exercise for year n
- ☐ Posts to be requested in the next APS/PDB procedure
- ☐ Posts to be redeployed using existing resources within the managing service (internal redeployment)
- ☐ Posts required for year n although not foreseen in the APS/PDB exercise of the year in question

<sup>68</sup> Cost of which is NOT covered by the reference amount

<sup>69</sup> Cost of which is NOT covered by the reference amount

<sup>70</sup> Cost of which is included within the reference amount

8.2.4. *Other Administrative expenditure included in reference amount (XX 01 04/05 – Expenditure on administrative management)*

EUR million (to 3 decimal places)

Budget line (number and heading)	Year n	Year n+1	Year n+2	Year n+3	Year n+4	Year n+5 and later	TOT AL
<b>1 Technical and administrative assistance (including related staff costs)</b>							
Executive agencies <sup>71</sup>							
Other technical and administrative assistance							
- <i>intra muros</i>							
- <i>extra muros</i>							
<b>Total Technical and administrative assistance</b>							

8.2.5. *Financial cost of human resources and associated costs not included in the reference amount*

EUR million (to 3 decimal places)

Type of human resources	Year n	Year n+1	Year n+2	Year n+3	Year n+4	Year n+5 and later
Officials and temporary staff (XX 01 01)	0.234	0.234	0.234	0.234	0.234	0.234
Staff financed by Art XX 01 02 (auxiliary, END, contract staff, etc.)  (specify budget line)						
<b>Total cost of Human Resources and associated costs (NOT in reference amount)</b>						

Calculation– *Officials and Temporary agents*

Rate of €17,000/ staff used to quantify the costs, as suggested in BUDG guidelines

<sup>71</sup> Reference should be made to the specific legislative financial statement for the Executive Agency(ies) concerned.



Calculation– *Staff financed under art. XX 01 02*

[...]

8.2.6. *Other administrative expenditure not included in reference amount*

EUR million (to 3 decimal places)

	Year n	Year n+1	Year n+2	Year n+3	Year n+4	Year n+5 and later	TOTAL
XX 01 02 11 01 – Missions							
XX 01 02 11 02 – Meetings & Conferences							
XX 01 02 11 03 – Committees <sup>72</sup>	0.200	0.200	0.200	0.200	0.200	0.200	1.200
XX 01 02 11 04 – Studies & consultations							
XX 01 02 11 05 - Information systems							
<b>2 Total Other Management Expenditure (XX 01 02 11)</b>	0.200	0.200	0.200	0.200	0.200	0.200	1.200
<b>3 Other expenditure of an administrative nature</b> (specify including reference to budget line)							
<b>Total Administrative expenditure, other than human resources and associated costs (NOT included in reference amount)</b>	0.200	0.200	0.200	0.200	0.200	0.200	1.200

Calculation - *Other administrative expenditure not included in reference amount*

[...]

The needs for human and administrative resources shall be covered within the allocation granted to the managing DG in the framework of the annual allocation procedure.

<sup>72</sup> Specify the type of committee and the group to which it belongs.