Directorate for Consultative Work

Unit 3 - *Networks & Subsidiarity*

EUROPEAN UNION

Committee of the Regions

REPORT ON THE CONSULTATION OF THE SUBSIDIARITY MONITORING NETWORK ON THE PROPOSAL FOR A DIRECTIVE ON THE APPLICATION OF PATIENTS' RIGHTS IN CROSS-BORDER HEALTHCARE

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http://subsidiarity.cor.europa.eu

Disclaimer:

The present report does not aim to reproduce all the contributions to the Subsidiarity Monitoring Network, but it tries to draw some main elements together. The remarks made here serve purely as an illustration, do not commit the CoR administration and do not prejudice the final content of the relevant CoR opinion.

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The consultation of the CoR Subsidiarity Monitoring Network on the Proposal for a Directive on patients' rights in cross-border healthcare ran between 1 September 2008 and 17 October 2008. A total of 17 Network Partners representing 10 EU Member States participated in the consultation by electronically submitting subsidiarity and proportionality analyses[1].

Analytical overview of the contributions received

1. Legal Basis

The majority of respondents agree with the choice of legal basis for the draft directive, and also mention the relevance of the proposal for the area of public health (Article 152 TEC). A particular reference is made to the requirement that EC action in the field of health should fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care (Art. 152 par. 5 TEC) [2]. One respondent considers that health services should not be addressed by pure market criteria and - albeit recognising that the ECJ jurisprudence which lead to the directive was based on the free movement of services - would have preferred if the Commission had emphasised Article 152 TEC more in its proposal.

Some partners question the general objective of the draft directive by arguing that the system envisaged is not compatible with their national health-care systems. They claim that such an implementation of patient mobility would be capable of putting in question the financial balance and the high standards of care of their care systems or would in fact undermine the national or regional competences for their planning and the financing.

2. Subsidiarity Principle

A majority of partners considers that the application of the principle of subsidiarity grants the Community a right to act within the field of the liberalisation of cross-border healthcare services. Some partners point to the fact that action on national or regional level alone would not be able to achieve the intended objectives, whilst others refer to the fact that the codification of existing case-law under Art. 49 TEC and the completion of the legal framework already present through Regulation 1408/71/EEC would serve as to enhance legal certainty and as to identify the rights and obligations of health-care systems, providers and recipients alike.

Nevertheless, doubts are expressed as to the following points:

- the Commission's competence to develop guidelines, which would specify the quality and safety standards of healthcare provided in the Member States (Art. 5 par. 3 of the proposal), is identified as implying a risk that quality and safety standards could potentially be harmonised at the lowest common denominator, whilst some partners claim that such a competence would in certain Member States fall under the responsibility of local and regional self-administration,

[1] For a list of the partners and their contributions see the Annex (in English).

[2] The ECJ has ruled that this requirement does not exclude the possibility of Member States having to make adjustments to their national social security systems C-372/04 *Watts*, European Court reports 2006 Page I-4325, par. 146-147.

- the prior authorisation procedure for hospital care and the related conditions provided for in article 8 (3) of the draft directive have been criticised as effectively reversing the burden of proof, making it necessary for the Member States to demonstrate on a case-by-case basis that the lack of a prior authorisation for the receipt of hospital care would seriously undermine the financial balance of the social security system, the planning or rationalisation of the hospital sector etc,
- a minority of partners claim that the existing legal framework (Art. 49 TEC and Regulation 1408/71/EEC) as well as the relevant case law are clear and precise enough, thus obviating the need for legislation, whereas reference is made to the fact that effective cross-border cooperation on health already exists.
- finally, the added value that the enactment of EU legislation would be thought to bring is being questioned on account of the fact that cross-border healthcare amounts to approximately 1% of total healthcare expenses.

3. Proportionality principle

Only a minority of the respondents consider that the draft directive does not go further than what is necessary to attain the intended objectives. They claim that the directive leaves adequate margin for manoeuvre to the national and regional administrations of the Member States, whilst it does not undermine their health and social security systems through its financial impact or through impinging on the planning and management of those systems. However, a significant proportion of respondents feel unable to give a clear evaluation of the proposal with relation to the proportionality principle by making reference to the lack of conclusive data.

The main concerns raised as to the compliance of the draft directive with the principle of proportionality are the following:

- the prior-authorisation procedure for the reimbursement of costs linked to hospital care received abroad (Article 8 par. 3 of the draft directive) is judged by some to be overly restrictive, in as much as they do not leave adequate room for national or regional decisions; others, however, consider that the same provisions are too vague and as such do not contribute to the enhancement of legal certainty,
- the information obligations contained in Article 5(1) point c of the directive are considered as being overly restrictive,
- the implementing competences (concerning inter alia the definition of complex treatments that can be in fact considered as hospital care, the identification and setting-up of European Reference Networks and taking specific measures for achieving the interoperability of information and communication technology in the health care field) reserved for the European Commission and set to be exercised through comitology committees are considered as going too far; in fact it is maintained that such implementing measures result in a quasi-legislative evolution of the directive and are consequently capable of having repercussions on the general conditions for healthcare in the Member States.

Finally, when asked to propose measures which would, in their opinion, provide less restrictive ways to achieve the intended objectives, some partners refer to simple information measures on the existing rights of patients, whilst others propose cross-border cooperation agreements between health-care providers in different Member States.

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4. Administrative and Financial Costs & Burdens

Respondents are unanimous that the implementation of the draft directive would involve administrative and/ or financial costs or burdens for the authorities involved at national, regional and local level. Although regard the costs associated with the implementation of the directive as being commensurate with its objectives, a number of partners highlight the lack of conclusive qualitative data that would allow them to make a detailed assessment of the costs to be incurred at their level. Difficulties which are inherent in any ex ante estimation of the costs connected with the directive due to the inability of the local and regional authorities to factor the "population variables" (i.e. the possible inflow and out-flow of patients) are also referred to.

Main elements identified are the following:

- increased costs possibly linked with the obligation to provide information to patients in different languages,
- an increase in costs borne by patients and their families possibly leading to a healthcare system which would differentiate between patients in terms of their resources could additionally exacerbate existing imbalances among regional healthcare systems,
- a particular impact on health systems funded exclusively through income tax.

5. Better Regulation & Preparation of the Proposal

A number of partners refer to the fact that the data supplied in the impact assessment cannot be regarded as conclusive or reliable, insofar as it does not take sufficiently into account differences between regions. Some responding partners have already participated in consultations at national or at EU level and underline the importance of consultations. Participation in the activities of the Subsidiarity Monitoring Network is also regarded as a form of consultation. With regard to the arguments put forward by the European Commission in order to justify the compliance of its proposal with subsidiarity and proportionality, most partners regard the quantitative data presented by the European Commission as being insufficient.

6. Further remarks

Asked to provide additional feedback on the proposal some network partners highlighted the following points:

- there is a need to hold further debates on patient mobility, aiming to enhance national, regional & local planning capacities and tools and involving local and regional authorities; reference is also made to Article 35 of the EU Charter of Fundamental Rights on health care, which is interpreted as mandating a further negotiation of the draft text with a view to giving it a more advanced vision and to achieving consensus between the Member States,
- the setting up of mechanisms or funds of an ad-hoc compensatory nature, which would mitigate the risk that treatments received in other Member States are finally not paid for by the Member States of affiliation is suggested,

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- finally, it is proposed to set a longer transposition deadline for the Member States, instead of the one-year period scheduled by the draft directive (Art. 22).

ANNEX OF PARTNERS' CONTRIBUTIONS

A total of 17 Network Partners representing 10 EU Member States submitted contributions[3,4]:

- Local Government Denmark (DK)
- Danish Regions (DK)
- Regional Parliament of Schleswig-Holstein (DE)
- German County Association (DE)
- Hellenic Parliament (EL)
- EU Delegation of the French Senate (FR)
- Catalan Parliament (ES)
- Basque Autonomous Parliament (ES)
- Basque Government (ES)
- Legislative Assembly of Emilia Romagna (IT)
- Tuscany Regional Council (IT)
- Regional Government of Lombardy (IT)
- Conference of Austrian State Governors (AT)
- Regional Parliament of Vorarlberg (AT)
- City of Lodz (PL)
- Regional Government of the Azores (PT)
- Association of Finnish Local and Regional Authorities (FI)

Five of the participating partners are regional parliaments, four are regional governments, one represents a city, while two are chambers of national parliaments. The remaining five represent associations of local and regional authorities within their respective Member State.

[3] A further Network Partner, the Parliament of the Principality of Asturias (ES), considered participating in the consultation, but in the end did not submit a contribution, due to the fact that the Commission in Charge of Healthcare Services had not received a statement from the Regional Government. Therefore the Asturian Parliament estimated that it needed more time to analyse the proposal.

[4] The Conference of Austrian State Governors and the State Parliament of Vorarlberg submitted identical contributions.

Local Government Denmark

1. Legal basis TYPE of competence:

1.1 Objective(s) of the document.

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.

1.2 On which Treaty article(s) is the document based? If you consider the legal basis inappropriate, please give reasons.

TEU art. 95.

1.3 Does the proposed action fall within the European Community's competences? Is such competence exclusive or shared between the Community and the Member States ?

The proposed action fall within the competences of the EC.

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2. Subsidiarity principle

2.1 Should action be taken at European level, because

(a) such action is necessary insofar as the Member States (either at the central or at regional and local levels) cannot sufficiently achieve the objective of the proposed measure, and

(b) such action would have a clear benefit by reason of its scale or effects?

Please provide a reasoned answer to the above question while giving consideration to the following:

i) whether the issue being addressed has trans-national aspects that cannot be properly regulated by action of Member States and/ or their local and regional authorities;

ii) whether action by Member States alone would conflict with the requirements of the Treaty or would otherwise significantly damage the Member States' interests;

iii) whether existing Community measures or targeted assistance provided hereunder would be sufficient to achieve the intended objectives.

a) The latest rulings of the European Court of Justice have made it necessary to provide a legal basis/clarification on this issue. Hence, Local Government Denmark supports the Commission's proposal regarding providing a legal basis. b.1) Yes, given the fact that the issue at stake concerns patient´s rights which in the Commission's proposal are defined as "cross-cutting the members state's borders".

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3. Proportionality principle:

3.1 Do the proposed measures go beyond what is necessary to satisfactorily achieve the intended objectives? Please provide a reasoned answer while giving consideration to the following elements:

i) whether the proposed form of action is as straightforward as possible (for example directives should be preferred to regulations and framework directives to detailed measures).

ii) whether the proposed action leaves as much room for national decision as possible.

iii) whether the proposed measures take account of well established national arrangements and special circumstances applying in your Member State or region (e.g. the organisation and functioning of the legal system).

Local Government Denmark does not find that the proposed measures go beyond what is necessary. LGDK finds that the framework directive is an appropriate tool.

3.2 If you consider that the proposed measures indeed go further than what is necessary, what would you consider to be a less restrictive, alternative way to achieve the intended objectives?

N/A

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4. Financial and/or administrative burden:

4.1 Please indicate whether the financial and/or administrative burden falling upon the European Community, national governments, regional and local authorities, economic operators and citizens is commensurate to the objectives of the proposal and whether it has been kept to an absolute minimum.

Yes, it will affect the regional and local authorities and LGDK is worried that the proposal will be costly for the Danish local and regional authorities. However, the present court rulings have already given the citizens a number of rights - hence a legal basis is very needed.

4.2 If the relevant data is available to you, please provide an estimation of the financial and/ or administrative burden the implementation of the present proposal would entail for your administration and/ or in the territory of your local or regional authority.

Local authorities find it very difficult to estimate the cost of the proposal.

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5. Consideration of local and regional factors in the impact assessment and consultation

5.1 Has a comprehensive impact assessment been presented, which takes into account local and

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regional aspects?

Not our knowledge.

5.2 Have local and regional authorities been adequately consulted prior to the adoption of the proposal? In case you have participated in such a consultation, please specify the practical details of your participation and provide an assessment of your experience.

Local Government Denmark has been consulted through the system of special committee on EU-issues which are coordinated by the Ministry of Health and the Ministry of Foreign Affairs. Local Government Denmark has on the 16. of July 2008 forwarded a hearing statement on the issue to the special committee. Further, Local Government Denmark, Danish Regions and the Ministry of Health have held meetings on the issue. The meetings have been held on the invitation of Danish Regions.

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6. Quality of the arguments provided:

6.1 Does the proposal provide clear, adequate and convincing arguments to justify its compliance with the subsidiarity and proportionality principles?

Yes, however the projections are based on great uncertainties as nobody knows to which extent patients will moved around for treatment, but there is a need for a legal base in this area.

6.2 Are these arguments based on qualitative as well as quantitative indicators?

There is a need for a legal base, but data is very insufficient on the matter and there is a need for more data - especially quantitative.

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7. Further comments

7.1 Please feel free to provide additional feedback on the overall quality of the proposal, i.e. clarity of drafting, simplicity of implementation at the regional and local level, need for a more thorough debate within the course of the legislative process on the financial/ and or administrative burden the proposal would entail, suitability of the envisaged action with regard to the intended objectives etc.

The legal system must take into account that local and regional authorities in charge of health care need clear and stable tools for planning, financing and organising. E.g. the Danish health care system is financed through taxes which provides a high quality heath care system for all citizens on an equal basis. But to be efficient the system needs effective planning tools.

Danish Regions

1. Legal basis TYPE of competence:

1.1 Objective(s) of the document.

The objective of the document is to create a community framework for cross-border healthcare.

1.2 On which Treaty article(s) is the document based? If you consider the legal basis inappropriate, please give reasons.

The document is based on the free market principles of TEU art. 95. Considering the debate in the European Parliament on the service directive, which resulted in the deletion of social and health services for the directive based on the argument, that such services were of a different character and should not be addressed by purely market related criteria, it is insufficient to base the directive on cross-border health care solely on TEU art. 95.
Acknowledging that the ECJ rulings which led to the directive, are based on art. 95, Danish Regions would have appreciated if the Commission had emphasized art. 152 more, stating that the responsibility for managing and organizing healthcare, rests solely within the member states.

1.3 Does the proposed action fall within the European Community's competences? Is such competence exclusive or shared between the Community and the Member States?
The proposed action does not fall completely within the European Community's competences. Depending on the interpretation of the text and the rulings of the ECJ, the proposed action from the Commission goes beyond the rulings of the ECJ on different aspects (i.e. differences in the interpretation of "reasonable time limits" for treatment). As mentioned in 1.2., the proposed action should have been better balanced between art. 152 and art. 95. The above mentioned actions are a shared responsibility between the Community and the Member State.

2. Subsidiarity principle

2.1 Should action be taken at European level, because
(a) such action is necessary insofar as the Member States (either at the central or at regional and local levels) cannot sufficiently achieve the objective of the proposed measure, and
(b) such action would have a clear benefit by reason of its scale or effects?
Please provide a reasoned answer to the above question while giving consideration to the following:

i) whether the issue being addressed has trans-national aspects that cannot be properly regulated by action of Member States and/ or their local and regional authorities;

ii) whether action by Member States alone would conflict with the requirements of the Treaty or would otherwise significantly damage the Member States' interests;

iii) whether existing Community measures or targeted assistance provided hereunder would be sufficient to achieve the intended objectives.

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With the rulings of the ECJ, it has become necessary to provide patients with adequate information on the consequences of the rulings concerning patient's rights. It is also necessary that the European Community takes political action and provides guidelines and rules set by politicians on this issue, not leaving it up to the ECJ to set the rules by individual examples, based on art. 95 of the Treaty an article that was not intended for health issues – hence the reason for article 152.

Thus the answer to (a) is yes with regard to the fact that not all member states have been able to achieve the standards set by the ECJ – otherwise there would not have been any ECJ rulings. However, many of the objectives in the directive could have been sufficiently achieved by action at central, regional or local level. There are plenty of examples of cross-border cooperation on health.
(b) The Commission itself estimates that cross-border patient mobility is approx 1 % today. Having this figure in mind it may be questioned if the proposed action is having a clear benefit by reason of its scale or effects. A major question is whether the proposed action will be beneficial for all patients in EU or just for the most resourceful.

3. Proportionality principle:

3.1 Do the proposed measures go beyond what is necessary to satisfactorily achieve the intended objectives? Please provide a reasoned answer while giving consideration to the following elements:

i) whether the proposed form of action is as straightforward as possible (for example directives should be preferred to regulations and framework directives to detailed measures).

ii) whether the proposed action leaves as much room for national decision as possible.

iii) whether the proposed measures take account of well established national arrangements and special circumstances applying in your Member State or region (e.g. the organisation and functioning of the legal system).

(i) As mentioned above, the proposed directive goes beyond the ECJ rulings on some aspects. This is a problem as the basis for the proposed directive is exactly the ECJ rulings.

(ii + iii) The proposed action does not leave sufficient room for national decisions i.e. on the organization and planning of cross-border treatment (i.e. the proposed requirements for prior authorization seems not to be flexible enough).

3.2 If you consider that the proposed measures indeed go further than what is necessary, what would you consider to be a less restrictive, alternative way to achieve the intended objectives?

The political will to provide clear rules in EU concerning cross-border healthcare can probably only be achieved through a community action. However, this should be done in respect of art. 152. Some of the objectives mentioned in the directive (i.e. centres of excellence, cooperation on e-health etc.) may be achieved without a directive.

4. Financial and/or administrative burden:

4.1 Please indicate whether the financial and/or administrative burden falling upon the European Community, national governments, regional and local authorities, economic

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operators and citizens is commensurate to the objectives of the proposal and whether it has been kept to an absolute minimum.

Depending very much on the development of patients mobility in EU, the proposed directive will have quite substantial impact on the financial and administrative burden falling on national, regional and local healthcare systems – especially in member states in which healthcare is financed through income tax. Furthermore there is a risk of creating differences between citizens and countries depending on their financial resources.

4.2 If the relevant data is available to you, please provide an estimation of the financial and/ or administrative burden the implementation of the present proposal would entail for your administration and/ or in the territory of your local or regional authority.

The data is not available.

5. Consideration of local and regional factors in the impact assessment and consultation

5.1 Has a comprehensive impact assessment been presented, which takes into account local and regional aspects?

The Commission has provided an impact assessment. However, it does not take sufficient account of local and regional aspects in some countries (i.e. the directives definition of hospital treatment which requires prior-authorization have to be more elaborate and should also include day-to-day treatment).

5.2 Have local and regional authorities been adequately consulted prior to the adoption of the proposal? In case you have participated in such a consultation, please specify the practical details of your participation and provide an assessment of your experience.

The association of Danish Regions represents the regional authorities in Denmark. Due to the importance of the proposal for a directive on cross-border health care, Danish Regions has been initiating meetings and consultations with the ministry of health, the regions and the local authorities on this issue. On the national level, therefore, regional authorities have been involved even before the official consultation normally launched by the ministry.

DG Sanco conducted, prior to the issuing of the directive, a consultation process in which Danish Regions took successfully part.

6. Quality of the arguments provided:

6.1 Does the proposal provide clear, adequate and convincing arguments to justify its compliance with the subsidiarity and proportionality principles?

As mentioned above, the directive goes further than the ECJ rulings within certain areas, which is problematic. Secondly, the directive deals with issues which could be managed between member states alone.

However, the part of the directive that aims at providing a clear set of rules, discussed and decided at the EU political level, concerning cross-border patient mobility within the specific cases of the ECJ rulings is in compliance with the subsidiarity and proportionality principles.

6.2 Are these arguments based on qualitative as well as quantitative indicators?

Yes, apart from being based on the rulings of the ECJ, the directive includes qualitative as well as quantitative indicators. The problem is how reliable these indicators are, as the directive attempts to set new rules for cross-border patient mobility in EU.

7. Further comments

7.1 Please feel free to provide additional feedback on the overall quality of the proposal, i.e. clarity of drafting, simplicity of implementation at the regional and local level, need for a more thorough debate within the course of the legislative process on the financial/ and or administrative burden the proposal would entail, suitability of the envisaged action with regard to the intended objectives etc.

It is very important to keep in mind that the Commissions proposal will set new rules for cross-border health care in EU. Apart from the aim of providing clear information to patients, the proposal will affect the management and organization of health care systems in the member states. Therefore the proposal needs to be discussed further in order to prevent that national, regional and local planning tools concerning health care, are not reduced – especially in countries where the health care system is financed through public tax.

Name of the Authority:	Regional Parliament of Schleswig-Holstein
Primary contact person:	
Title of document:	Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare
Reference: **COM(2008) 414**	COM(2008) 414 final; Council document: 11307/08

1. Legal basis and type of competence: a) Objective(s) of the document. b) On which Treaty article(s) is the document based? If you consider the legal basis inappropriate, please give reasons. c) Does the proposed action fall within the European Community's competences? Is such competence exclusive or shared between the Community and the Member States[5]?	a) (Sufficient) clarity on patients' rights to reimbursement for healthcare provided in another Member State A safeguard "that the necessary requirements for high-quality, safe and efficient healthcare are ensured for cross-border care". b) Article 95 of the EC Treaty (establishment and functioning of the internal market) c) Under Article 152 of the EC Treaty, this is a competence to supplement, coordinate or support the actions of the Member States

2. Subsidiarity principle Should action be taken at European level, because: a) such action is necessary insofar as the Member States (either at the central or at regional and local levels) cannot sufficiently achieve the objective of the proposed measure, and b) such action would have a clear benefit by reason of its scale or effects? Please provide a reasoned answer to the above question while giving consideration to the following:	Action at European level is appropriate, in view of the principles set out in Article 152 of the EC Treaty. In terms of developing national health policies based on extensive ECJ case law, there is an intrinsic need for coordinating and supplementary action at European level. This will ensure legal certainty for patients,

5 If the competence is exclusive, the subsidiarity principle does not apply. If this is the case, please go directly to the proportionality section of this questionnaire.

i) whether the issue being addressed has trans-national aspects that cannot be properly regulated by action of Member States and/ or their local and regional authorities; ii) whether action by Member States alone would conflict with the requirements of the Treaty or would otherwise significantly damage the Member States' interests; iii) whether existing Community measures or targeted assistance provided hereunder would be sufficient to achieve the intended objectives.	doctors and health insurance providers.

3. Proportionality principle a) Do the proposed measures go beyond what is necessary to satisfactorily achieve the intended objectives? Please provide a reasoned answer while giving consideration to the following elements: i) whether the proposed form of action is as straightforward as possible (for example directives should be preferred to regulations and framework directives to detailed measures); ii) whether the proposed action leaves as much room for national decision as possible; iii) whether the proposed measures take account of well established national arrangements and special circumstances applying in your Member State or region (e.g. the organisation and functioning of the legal system). b) If you consider that the proposed measures indeed go further than what is necessary, what would you consider to be a less restrictive, alternative way to achieve the intended objectives?	a) Yes. Some of the provisions go too far and encroach on competences which are reserved for the Member States. Article 5 is very specific on **quality and safety standards as well as liability issues** for healthcare services in the Member States. In this context, the proposed directive also encroaches on national responsibilities for the organisation of healthcare. In Germany, quality assurance is to a large extent self-managed. Under current circumstances at least, a supervisory body would not be able to ensure quality standards, as stipulated by the proposal. Article 5(1)(c) requires Member States to ensure that healthcare providers provide patients with all information on availability, prices and outcomes of the healthcare provided and details of their insurance cover, professional liability, etc. Admittedly, Member States do have the option under Article 8(3) to provide for a system of authorisation for inpatient

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	treatment. However, for outpatient treatment that requires use of highly specialised and cost-intensive medical infrastructure, Article 8(2) stipulates that authorisation may be required only on the basis of a list drawn up under the comitology procedure. The directive confers very substantial powers on the comitology committee (Article 19), for example in relation to identifying and developing networks of reference centres (Article 15), and to specific measures necessary for achieving the interoperability of national information and communication technology systems. Admittedly, in principle it is conceivable that the EU could play a stronger coordinating role, possibly also through the comitology committee. However, the role of the comitology committee under the proposed directive must be scrutinised very critically, given the scope for the ongoing quasi-legislative development of the directive and consequently of the general conditions for healthcare in the Member States.

4. Financial and/or administrative burden: a) Please indicate whether the financial and/or administrative burden falling upon the European Community, national governments, regional and local authorities, economic operators and citizens is commensurate to the objectives of the proposal and whether it has been kept to an absolute minimum. b) If the relevant data is available to you, please provide an estimation of the financial and/or administrative burden the implementation of the present proposal would entail for your administration and/or in the territory of your local or regional authority.	a) Article 18 requires Member States to submit statistical and other data on cross-border healthcare to the Commission every year. Depending on the scope involved, the collection of such data could create additional burdens. Depending on what form they take, the national contact points intended to provide patients with information on cross-border healthcare and help them to protect their rights are likely to involve additional costs (Article 12).

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Better Regulation and Preparation of the proposal	
5. Consideration of local and regional factors in the impact assessment and consultation: a) Has a comprehensive impact assessment been presented, which takes into account local and regional aspects? b) Have local and regional authorities been adequately consulted prior to the adoption of the proposal? In case you have participated in such a consultation, please specify the practical details of your participation and provide an assessment of your experience.	
6. Quality of the arguments provided: a) Does the proposal provide clear, adequate and convincing arguments to justify its compliance with the subsidiarity and proportionality principles? b) Are these arguments based on qualitative as well as quantitative indicators?	
Further comments Please feel free to provide additional feedback on the overall quality of the proposal, i.e. clarity of drafting, simplicity of implementation at the regional and local level, need for a more thorough debate within the course of the legislative process on the financial/ and or administrative burden the proposal would entail, suitability of the envisaged action with regard to the intended objectives etc.	In practice, overlap between this directive and the provisions of Regulation 1408 could cause problems. Although the regulation has precedence over the directive, the fact that these two legal acts have different legal bases and must therefore be applied in different ways makes it difficult to delineate clearly between them. In general, as clear a distinction as possible should be drawn between laws on services with directly related scope. In Germany, examples would be medical rehabilitation services for people with a disability, long-term care services, social welfare services or care provision for war victims.

Deutscher Landkreistag

1. Legal basis and type of competence:

1.1 Objective(s) of the document.

The objectives of the document appear reasonable, but are too broad in their scope and are thus not strictly necessary.

1.2 On which Treaty article(s) is the document based? If you consider the legal basis inappropriate, please give reasons.

Fundamentally no objections

1.3 Does the proposed action fall within the European Community's competences? Is such competence exclusive or shared between the Community and the Member States?

The EU has only subsidiary competence in this area; the arrangements in the Member States take precedence. However, the EU can replace multilateral agreements where there is consensus for this among the Member States.

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2. Subsidiarity principle

2.1 Should action be taken at European level, because: a) such action is necessary insofar as the Member States (either at the central or at regional and local levels) cannot sufficiently achieve the objective of the proposed measure, and
b) such action would have a clear benefit by reason of its scale or effects?

Please provide a reasoned answer to the above question while giving consideration to the following:

i) whether the issue being addressed has trans-national aspects that cannot be properly regulated by action of Member States and/ or their local and regional authorities;
ii) whether action by Member States alone would conflict with the requirements of the Treaty or would otherwise significantly damage the Member States' interests;
iii) whether existing Community measures or targeted assistance provided hereunder would be sufficient to achieve the intended objectives.

It cannot be said that all of the proposed measures can best or exclusively be implemented by the EU. Overall, a much stricter measure needs to be used for subsidiarity monitoring.

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3. Proportionality principle

3.1 Do the proposed measures go beyond what is necessary to satisfactorily achieve the intended objectives? Please provide a reasoned answer to the above question while giving consideration to the following:

i) whether the proposed form of action is as straightforward as possible (for example directives should be preferred to regulations and framework directives to detailed measures);

ii) whether the proposed action leaves as much room for national decision as possible;

iii) whether the proposed measures take account of well established national arrangements and special circumstances applying in your Member State or region (e.g. the organisation and functioning of the legal system).

For example: the possibility of the Commission regulating treatment centres in hospitals for certain illnesses goes too far; this is an unnecessary step that would be better handled in the Member States.

3.2 If you consider that the proposed measures indeed go further than what is necessary, what would you consider to be a less restrictive, alternative way to achieve the intended objectives?

Handling hospital planning in the Member States

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4. Financial and/or administrative burden:

4.1 Please indicate whether the financial and/or administrative burden falling upon the European Community, national governments, regional and local authorities, economic operators and citizens is commensurate to the objectives of the proposal and whether it has been kept to an absolute minimum.

The administrative burden for the German *Landkreise*, in the light of their competence as hospital providers and as guarantors of in-patient medical treatment, cannot yet be definitively established.

4.2 If the relevant data is available to you, please provide an estimation of the financial and/or administrative burden the implementation of the present proposal would entail for your administration and/or in the territory of your local or regional authority.

See above.

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5. Consideration of local and regional factors in the impact assessment and

consultation:

5.1 Has a comprehensive impact assessment been presented, which takes into account local and regional aspects?

No, not yet possible

5.2 Have local and regional authorities been adequately consulted prior to the adoption of the proposal? In case you have participated in such a consultation, please specify the practical details of your participation and provide an assessment of your experience.

Yes. *Landkreise* were informed; discussion and decision in the competent committee of the Deutscher Landkreistag

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6. Quality of the arguments provided:

6.1 Does the proposal provide clear, adequate and convincing arguments to justify its compliance with the subsidiarity and proportionality principles?

n/a

6.2 Are these arguments based on qualitative as well as quantitative indicators?

n/a

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7. Further comments

7.1 Please feel free to provide additional feedback on the overall quality of the proposal, i.e. clarity of drafting, simplicity of implementation at the regional and local level, need for a more thorough debate within the course of the legislative process on the financial/ and or administrative burden the proposal would entail, suitability of the envisaged action with regard to the intended objectives etc.

Name of the Authority:	Hellenic Parliament
Primary contact person:	
Title of document:	Proposal for a directive of the European Parliament and the Council on the application of patients' rights in cross border healthcare
Reference: **(e.g. COM(2005)112)**	COM (2008) 414

1. Legal basis & type of competence:	
a) Objective(s) of the document.	a) The objective of the proposed directive is to facilitate factor mobility (in the form of patient mobility), so as to enhance the efficient operation of the single European market. The means to achieve this is by enabling patients to seek treatment in another EU member-state and be reimbursed for that, as if they were treated at their home country. To this end, the directive sets a clear framework of rights as well as minimum quality standards.
b) On which Treaty article(s) is the document based? If you consider the legal basis inappropriate, please give reasons.	b) The legal basis is appropriate. It relies on Article 95 of the EC Treaty on the convergence of national legislative acts necessary for the establishment and functioning of the internal market.
c) Does the proposed action fall within the European Community's competences? Is such competence exclusive or shared between the Community and the Member States[6]?	c) The proposed action falls in the domain of shared competences between the European Union and member-states. For that reason, a compliance check of the principle of subsidiarity is necessary.

2. Subsidiarity principle	
Should action be taken at European level, because (a) such action is necessary insofar as the Member States (either at the central or at regional and local levels) cannot sufficiently achieve the objective of the proposed measure,	i) The proposed action only codifies and integrates existing case law of the ECJ. Its raison d' être is to organise collectively and efficiently cross-border aspects of health treatment within the single European market. That is to say, the proposed action regulates

[6] If the competence is exclusive, the subsidiarity principle does not apply. If this is the case, please go directly to the proportionality section of this questionnaire.

.../...

and (b) such action would have a clear benefit by reason of its scale or effects? Please provide a reasoned answer to the above question while giving consideration to the following: i) whether the issue being addressed has trans-national aspects that cannot be properly regulated by action of Member States and/ or their local and regional authorities; ii) whether action by Member States alone would conflict with the requirements of the Treaty or would otherwise significantly damage the Member States' interests; iii) whether existing Community measures or targeted assistance provided hereunder would be sufficient to achieve the intended objectives.	existing patterns of patient choices. In that respect, it enhances subsidiarity, as it is necessary in order to ameliorate the capacity of national governments to run their social security and health systems by internalising through cooperation cross-border externalities. ii) If such a cooperation were not sought through the proposed draft directive and national interests were not accordingly aligned at a minimum in this particular policy domain, then national action could indeed conflict with either other member-states' interests or with the Treaty. iii) Given the principle of subsidiarity, the proposed action would suffice to meet the intended objectives which relate to observed (ex post) patient behaviour.

3. Proportionality principle: a) Do the proposed measures go beyond what is necessary to satisfactorily achieve the intended objectives? Please provide a reasoned answer while giving consideration to the following elements: i) whether the proposed form of action is as straightforward as possible (for example directives should be preferred to regulations and framework directives to detailed measures). ii) whether the proposed action leaves as much room for national decision as possible. iii) whether the proposed measures take account of well established national arrangements and special circumstances applying in your Member State or region (e.g. the organisation and functioning of the legal system). b) If you consider that the proposed measures indeed go further than what is necessary, what would you consider to be a less restrictive, alternative way to achieve the intended objectives?	The proposed draft directive is complementary to existing legislation and straightforward in its scope of action. Cross-border patient mobility entails externalities which cannot be tackled at the national level. In that respect, EU action is required. The proposed EU action is limited to that particular dimension of health treatment (i.e. the modalities of cross-border patient mobility). In general, however, lack of consistent, comparable, regularly updated and reliable data on patient mobility across the EU (no patient-mobility data-base) distorts our knowledge of the actual breadth and depth of the problem that the draft directive under scrutiny endeavours to tackle. In that respect, the explicit assessment of the proportionality of the means put into place by this draft directive in order to attain the stated objective retains a degree of obscurity, so far as that objective is other than necessary legal certainty and clarity in a particular EU-wide policy domain. As a final comment, the suggested policy means remain at the lowest possible level, apparently with a view to not interfering with the principle of proportionality.

.../...

4. Financial and/or administrative burden:	
a) Please indicate whether the financial and/or administrative burden falling upon the European Community, national governments, regional and local authorities, economic operators and citizens is commensurate to the objectives of the proposal and whether it has been kept to an absolute minimum.	a) The proposed directive entails a series of administrative rearrangements in our national health system, some of which are expected to have a considerable financial burden. However, all these actions are considered to be necessary for modernising the system and improving the supply of health services.
b) If the relevant data is available to you, please provide an estimation of the financial and/ or administrative burden the implementation of the present proposal would entail for your administration and/ or in the territory of your local or regional authority.	b) There is no consistent data available at this point in time.

Better Regulation & Preparation of the proposal	
5. Consideration of local and regional factors in the impact assessment and consultation	
a) Has a comprehensive impact assessment been presented, which takes into account local and regional aspects?	a) As mentioned above, an impact assessment relying on consistent statistical data would have ameliorated our evaluation of the proposal for a directive.
b) Have local and regional authorities been adequately consulted prior to the adoption of the proposal? In case you have participated in such a consultation, please specify the practical details of your participation and provide an assessment of your experience.	

6. Quality of the arguments provided: a) Does the proposal provide clear, adequate and convincing arguments to justify its compliance with the subsidiarity and proportionality principles? b) Are these arguments based on qualitative as well as quantitative indicators?	a) The arguments are detailed and convincing. b) Quantitative indicators –especially for justification of proportionality- are deemed to be inadequate.
Further comments Please feel free to provide additional feedback on the overall quality of the proposal, i.e. clarity of drafting, simplicity of implementation at the regional and local level, need for a more thorough debate within the course of the legislative process on the financial/ and or administrative burden the proposal would entail, suitability of the envisaged action with regard to the intended objectives etc.	

Senate Delegation for the European Union

CROSS-BORDER HEALTHCARE PATIENT RIGHTS

COM(2008) 414 final

Subject:

The European Commission has drawn up a proposal for a directive which aims at ensuring a clear, transparent framework for the provision of cross-border healthcare within the EU, i.e. for those occasions where the care patients seek is provided in another Member State than in their home country.

It will be recalled that although the first version of the proposal for a directive on services in the internal market – known as the "services directive" – had included health services, in the end they were excluded from its field of application. The present document, of necessity less ambitious, now constitutes a new Commission initiative to dismantle barriers to cross-border healthcare provision.

The proposal for a directive should make it possible to establish common principles for all the European Union's healthcare systems, to clarify the rules applicable to cross-border healthcare provision – especially by codifying the rulings of the Court of Justice of the European Communities (CJEC) in this area – and to improve and formalise European cooperation in healthcare.

The aim is two-fold:

1) to have clear, reliable rules about reimbursement for healthcare provided in other Member States;

2) to ensure that cross-border care meets the necessary requirements for high-quality, safe and efficient healthcare.

This proposal would alter neither the current regulatory framework for the coordination of social security schemes provided by Regulation 1408/71 (EEC), nor that for the mutual recognition of professional qualifications established by Directive 2005/36/EC.

The Commission's rationale regarding subsidiarity and proportionality:

The Commission refers to the subsidiarity principle a number of times when discussing the general legal aspects:

– Firstly, it makes clear that although its proposal is based on Article 95 of the Treaty regarding the operation of the internal market, it "fully respect[s] the responsibilities of the Member States for the organisation and delivery of health services and medical care". It also asserts that "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". The proposal for a directive "respects the fact that health systems are primarily the responsibility of Member States".

– Secondly, it makes some more detailed specific points in relation to the principle of subsidiarity. It takes the view that questions raised by its proposal "cannot be addressed by the Member States alone". Although it points out that, under Article 152 of the EC Treaty, Community action in the field of public health must fully respect the responsibilities of the Member States, this provision, according to ECJ rulings, "does not, however, exclude the possibility that the Member States may be required […] to make adjustments to their national healthcare and social security systems". It adds that "this does not mean that this undermines their sovereign powers in the field".

As regards the principle of proportionality, the European Commission indicates that its 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". Its directive would thus in no way erode the responsibilities of the Member States.

Some comments on subsidiarity and proportionality:

The Commission's proposal for a directive could have enormous repercussions. The difficult and protracted discussions on the "services directive" revealed that, by their very nature and because their purpose is in the general interest, healthcare services cannot be considered as ordinary services. Those debates served, in fact, to affirm the distinct character of these services.

There are considerable, widely shared doubts regarding the proposed directive's compliance with the subsidiarity and proportionality principles.

Differences have emerged among the Commissioners themselves, requiring the adoption of the document to be deferred a number of times. Initially scheduled for adoption at the beginning of November 2007 and then announced for 19 December, it was finally adopted on 2 July 2008. Some Commissioners had voiced grave misgivings about the proposal, believing it did not respect national responsibilities in the matter. Successive changes to the wording are a reflection of tough discussions during the interdepartmental consultations.

While the Member States, for their part, acknowledge the importance of having a legal framework codifying the principles handed down by the ECJ, they have repeatedly insisted on the need to preserve their competencies in this sensitive area. Most of them think, for example, that the reimbursement of hospital care in another Member State must remain contingent upon prior authorisation issued at the national level. Attempting to balance the budgets of healthcare and social security systems and planning care provision are crucial matters for the Member States. It is absolutely vital, therefore, that they continue to be able to manage patient flows.

The European Parliament, which is naturally aware of the political sensitivity of the matter, has made exactly the same points.

To take on board these criticisms and concerns, the Commission's final document has:

- reaffirmed the responsibility of the Member States for organising health systems and the delivery of medical care (Article 5.1);
- reinstated the possibility for a Member State to stipulate prior authorisation of the cost of hospital care when two conditions are met: 1) where the costs would be covered by its social security system if the treatment were to be provided on its territory, and 2) where applying this provision does not, or is not likely to, seriously undermine the financial balance of its social security system or hospital sector planning (by leading to hospital overcapacity, for example) (Article 8.3).

While these are highly desirable changes, the proposal nevertheless continues to pose a certain number of difficulties, especially regarding two points.

Firstly, although the reaffirmation in Article 5.1 of the Member States' responsibilities is welcome, it nevertheless goes beyond the terms of reference.

The wording of this article still seems to pay insufficient heed to the subsidiarity principle. Article 5.3, in fact, grants the Commission powers to "develop guidelines" that enable it to facilitate the definition by Member States of quality and safety standards applicable to healthcare provided in their countries. The loose drafting makes it impossible to distinguish exactly what the Commission's role will be. Will it be able to go so far as to set healthcare quality and safety standards? If so, given the great diversity of circumstances in the European Union, there would be a risk of harmonisation "downwards".

Secondly, the conditions set out in Article 8.3 for the establishment of prior authorisation for the reimbursement of hospital care are based on a broad interpretation of the principles handed down by the ECJ and hence go beyond a codification exercise. The Court set out a principle of general justification for prior approval for hospital care, namely overriding reasons of general interest (such as the risk of serious detriment to the balance of a social security system's accounts, public health reasons or problems relating to hospital service access).

The Commission is in a sense moving to reverse the burden of proof in proposing that the Member State should have to prove, in each case, how the lack of prior authorisation would imperil the financing and organisation of care. This would, of course, be very complicated. Moreover, the drafting is also porous. How, for instance, is the seriousness of the detriment to the financial balance or the planning of the system to be gauged?

It is also rather difficult to assess compliance with the proportionality principle as set out in the proposal.

As suggested above, the Commission has on occasions gone beyond affirming general principles.

Above all, it seems difficult to grasp the practical scope of the document, given the complete or partial absence of statistical data. Patient mobility in the European Union is still very limited (though probably set to rise) and remains at present a little known phenomenon. For this reason, care should

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be taken in predicting its practical consequences, whether good or bad. The summary of the impact analysis provided by the Commission to support its document has little to say on this matter.

Draft remarks

Proposal for a Directive on the application of patients' rights in cross-border healthcare COM(2008) 414 final

* * *

The Senate delegation for the European Union believes that, in order to comply with the principles of subsidiary and proportionality, the proposal must give tangible substance to the reaffirmation of the responsibilities of Member States in the organisation and provision of healthcare.

To that end:

- Article 5.3 of the proposal – which enables the European Commission to develop guidelines to facilitate the definition by Member States of quality and safety standards applicable to healthcare provided in their countries – should be deleted;
- Article 8.3 of the proposal should be amended to provide that only the Member States can assess the seriousness of risk to the financing and organisation of healthcare, as regards establishing prior authorisation for the reimbursement of hospital care.

In addition, the Senate delegation for the European Union would like the European Commission to make its impact assessment more comprehensive in order to provide better information on which to assess the document's implications.

This document is available at:

http://www.senat.fr/europe/textes_europeens/e3903.pdf

Name of the Authority:	Parliament of Catalunya
Primary contact person:	Marcel Riera; Miquel Palomares
Title of document:	Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare
Reference: **(e.g. COM(2005)112)**	COM(2008) 414 final

1. Legal basis & type of competence: a) Objective(s) of the document.	The objective of the directive is to establish a general legal framework for providing cross-border health care in order to guarantee (i) the obligations of the Member States and health service providers, and (ii) the rights of European citizens in this specific area.
b) On which Treaty article(s) is the document based? If you consider the legal basis inappropriate, please give reasons.	The legal basis, ECT Article 95 is appropriate insofar as the basic aim of the directive is the approximation of legislation in the specific field of cross-border healthcare. In addition, the directive could also be explicitly based on ECT Article 152(2) insofar as provisions are established with a view to facilitating cooperation in the area of public health (Articles 13, 14, 15, 16 and 17).
c) Does the proposed action fall within the European Community's competences? Is such competence exclusive or shared between the Community and the Member States[7]?	The approximation of legislation to the extent necessary for the operation of the common market, and cooperation in the area of public health are, according to the founding Treaties and the interpretation of the Court of Justice of the European Communities, a competence shared between the EU and the Member States. In the case of Spain, the autonomous regions have competences in the field of provision of health services.

[7] If the competence is exclusive, the subsidiarity principle does not apply. If this is the case, please go directly to the proportionality section of this questionnaire.

2. Subsidiarity principle	
Should action be taken at European level, because (a) such action is necessary insofar as the Member States (either at the central or at regional and local levels) cannot sufficiently achieve the objective of the proposed measure, and (b) such action would have a clear benefit by reason of its scale or effects?	The EU's legislative action may be considered to be necessary insofar as the Member States cannot sufficiently achieve the objective of the proposed measure Similarly, the scale and effects of the EU's legislative action can provide greater effectiveness than the individual action of the Member States.
Please provide a reasoned answer to the above question while giving consideration to the following:	
i) whether the issue being addressed has trans-national aspects that cannot be properly regulated by action of Member States and/ or their local and regional authorities;	The directive's objective has trans-national aspects that cannot be properly regulated by the Member States alone.
ii) whether action by Member States alone would conflict with the requirements of the Treaty or would otherwise significantly damage the Member States' interests;	Approximation of legislation is by nature a trans-national competence, of a purely Community nature, created by the founding Treaties.
iii) whether existing Community measures or targeted assistance provided hereunder would be sufficient to achieve the intended objectives.	The need for the directive is borne out by the absence of express legal rules in this framework. Legislative action in this specific area would provide greater legal certainty. In this regard, the general principles relating to the internal market and the case-law of the Court of Justice of the European Community do not provide a sufficiently clear and precise legal basis to guarantee citizens' rights.

3. Proportionality principle:	
a) Do the proposed measures go beyond what is necessary to satisfactorily achieve the intended objectives? Please provide a reasoned answer while giving consideration to the following elements:	The proposed legislative measures do not go beyond the obligations flowing from the principle of subsidiarity. Directives are a legislative category that is

.../...

i) whether the proposed form of action is as straightforward as possible (for example directives should be preferred to regulations and framework directives to detailed measures). ii) whether the proposed action leaves as much room for national decision as possible. iii) whether the proposed measures take account of well established national arrangements and special circumstances applying in your Member State or region (e.g. the organisation and functioning of the legal system).	appropriate to the objective of approximating legislation insofar as the aim is harmonisation. The proposal for a directive only lays down the general principles constituting the EU framework in this area, but leaves considerable room for manoeuvre for the Member States to apply these principles in accordance with national, regional or local circumstances. Article 11, for example, provides that healthcare service is to be provided according to the legislation of the Member State of treatment. The proposal respects the responsibilities of the Member States in the area of organising, financing and delivering health services and medical care. It does not affect the right of the Member States to define the health care provision that they may have decided to offer to their citizens, although it may give rise to some undesirable practices, which is why it must be discussed in detail.
b) If you consider that the proposed measures indeed go further than what is necessary, what would you consider to be a less restrictive, alternative way to achieve the intended objectives?	The proposed measures do not go further than necessary. However, we believe that the text should be improved during the procedure leading up to adoption, as set out in the present assessment.

4. Financial and/or administrative burden: a) Please indicate whether the financial and/or administrative burden falling upon the European Community, national governments, regional and local authorities, economic operators and citizens is commensurate to the objectives of the proposal and whether it has been kept to an absolute minimum.	The directive provides that the maximum amount to be reimbursed by patients in another Member State is that laid down by the legislation of the Member State of which the patient is a national. Similarly, provision is made in certain cases for prior authorisation to cover hospital costs. However, the directive does not analyse the financial impact of providing such health services on the receiving Member State. From this point of view, repercussions are to be expected on the financial balance of the health systems in the

.../...

	predominantly receiving Member States unless a European health compensation fund is set up (which could be done by a subsequent regulation) and the payment and pricing system is clarified. Without a prior authorisation system, it is impossible to properly organise and plan a national health system. Patients should not travel on their own initiative to seek a particular health service in other Member States: rather the health service of the sending state should forward the patient to the receiving state. There is a need to assess the impact of lengthening waiting lists in the Member States. Moreover, advance payment by patients and the lack of funding to cover ancillary costs such as travel and accommodation for patients and family members will only benefit those with greater resources and could give rise to a two-speed health system in which those who have enough resources to pay travel and hospitalisation expenses will get treatment first. In this respect, one way of avoiding greater and unnecessary transaction charges would be to make use of the existing international compensation system between social security systems to deal with the funding required in each case. Neither should the difficulty of providing cross-border health care in the event of different languages be underestimated. This aspect requires resources if a proper solution is to be found.
b) If the relevant data is available to you, please provide an estimation of the financial and/ or administrative burden the implementation of the present proposal would entail for your administration and/ or in the territory of your local or regional authority.	The precise effects in terms of numbers of individuals concerned or financial resources are unknown. The Spanish government has official data from the forms sent to Social Security concerning migrant workers, but there is no information on patients who instead of using public health services, use those covered by their travel insurance (Europassistance etc.), or purely private patients who – although not having an impact on the national health service – do affect

	the overall health system.

Better Regulation & Preparation of the proposal	
5. Consideration of local and regional factors in the impact assessment and consultation a) Has a comprehensive impact assessment been presented, which takes into account local and regional aspects?	No, the impact assessment only assesses the cost of functions performed by the EC, and does not include the possible impact on the Member States' health systems, considering this to be minor. The impact at regional or local level is of course not assessed either.
b) Have local and regional authorities been adequately consulted prior to the adoption of the proposal? In case you have participated in such a consultation, please specify the practical details of your participation and provide an assessment of your experience.	In connection with this directive, the Parliament of Catalunya has only been consulted in this case. The Spanish Ministry for Health and Consumer Affairs invited the autonomous regions to a meeting to discuss the state of progress of the draft directive on the application of patients' rights in cross-border healthcare and to receive their comments and suggestions. The autonomous regions asked to be kept informed on the national government's work and views on the matter. The autonomous regions unanimously agreed to forge a consensus position with the Spanish Ministry for Health and Consumer Affairs.
6. Quality of the arguments provided: a) Does the proposal provide clear, adequate and convincing arguments to justify its compliance with the subsidiarity and proportionality principles?	The directive does not provide explicit arguments to justify its compliance with the subsidiarity and proportionality principles; these are to be deduced from the objectives and content of the directive's articles.
b) Are these arguments based on qualitative as well as quantitative indicators?	The directive does not provide quantitative indicators regarding its financial and organisational impact in the Member States. It only provides a financial statement regarding EU administrative aspects.
Further comments Please feel free to provide additional feedback on the overall quality of the proposal, i.e. clarity of drafting, simplicity of implementation at the	There should be a more in-depth discussion of the administrative and financial consequences of implementing the directive at regional and local

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regional and local level, need for a more thorough debate within the course of the legislative process on the financial/and or administrative burden the proposal would entail, suitability of the envisaged action with regard to the intended objectives etc.	level. The wording of some articles lacks clarity (e.g. Article .3). As a general comment, it would be better to envisage a "health services" directive rather than a "patients" directive, providing criteria for a common approach to tackling the challenges facing the Member States' health systems in areas such as coordination of alerts and emergencies, coordination of health promotion policies, quality guarantee arrangements, etc. A key point in the application of the directive for our country will be compliance with the present organisational structure of the Spanish health system, in which the autonomous communities have the ultimate responsibility for delivering health services to citizens. We believe that the guarantee of a high level of health protection, as laid down in Article 35 of the Charter of fundamental rights of the EU, means that the text needs further negotiation to give it a more advanced vision of health protection that is a product of greater agreement with the Member States.

Basque Autonomous Parliament

EUSKO LEGEBILTZARRA
PARLAMENTO VASCO

OSASUN BATZORDEA
COMISIÓN DE SANIDAD

THE BASQUE PARLIAMENT'S HEALTH COMMISSION'S REPLY TO THE COMMITTEE OF REGION'S QUESTIONNAIRE ON ASSESSING SUBSIDIARITY AND PROPORTIONALITY PRINCIPLES IN HEALTH MATTERS (Third test promoted by The Committee of the Regions)

Having analysed the following documents:

1. Draft directive from the European Parliament and Council on the application of patients rights in cross-border health care. COM (2008) 414 final.

2. Communication from the Commission on a community framework on the application of patient's rights in cross-border health care. COM (2008) 415.

3. Accompanying document from the Commission's services to the draft directive from the European Parliament and Council on the application of patients rights in cross-border health care – "Impact assessment". SEC (2008) 2164.

4. Analytical report on cross-border health care in the European Union (Flash Eurobarometer – Series 210).

5. Comunication from the Commission on the follow-up to the high-level reflection process on patient mobility and healthcare developments in the European Union. COM (2004) 301.

6. Communication from the Commission, to the Council, the European Parliament, The European Economic and Social Committee and the Committee of the Regions on modernizing social protection for the development of high-quality, accessible and sustainable health-care and long-term care: support for the national strategies using the "open method of co-ordination" COM (2004) 304.

7. Ruling of the European Economic and Social Committee on patients rights. SOC/221.

8. Ruling of the European Economic and Social Committee on the Communication from the Commission - follow-up to the high-level reflection process on patient mobility and healthcare developments in the European Union. SOC/179.

9. Ruling of the European Economic and Social Committee on the White Paper – Together for health : a strategic approach for the EU (2008-2013) SOC/294.

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.../...

10. Ruling of the Committee of the Regions of the 30th September 2004 on the Communication from the Commission regarding the follow-up to the high-level reflection process on patient mobility and healthcare developments in the European Union and on the Communication from the Commission to the Council, the European Parliament, The European Economic and Social Committee and the Committee of the Regions on modernizing social protection for the development of high-quality, accessible and sustainable health-care and long-term care: support for the national strategies using the "open method of co-ordination". ECOS-035.

11. Reports prepared by the Basque Government's Health Department and European Affairs Office of the Secretary General for Overseas Action,

And having listened, on the 6th October 2008, to the parliamentary appearances of the Directors of the Office of Support, Studies and Healthcare Development and the Director of Finance and Health Contraction from the Health Department and the Director of Euopean Affairs of the Basque Government's Secrteary General for Overseas Action.

The Basque Parliament's Health Commission replies to the questionnaire on assessing the subsidiarity and proportionality principles prepared by the Committee of Regions within the pilot test of the subsidiarity control network (third test promoted by the Committee of the Regions).

1. <u>Legal Basis and type of jurisdiction</u>

a) Objectives of the document

The draft Directive on the application of patients' rights in cross-border healthcare, which is the object of this resolution, aims to create a community framework for providing said cross-border healthcare by eliminating the barriers to freedom of patient movement and enforcing in cross-border healthcare, the necessary quality, security and efficiency requirements.

To achieve these aims, the draft looks in to the following fields:

- The principles that are common to all the EU members' healthcare systems.
- A specific framework for cross-border healthcare.
- European Co-operation in the field of healthcare.

The draft Directive is divided into the following 5 chapters:

General provisions: here, amongst other matters, the objective, scope of application and definitions to be used in the draft's text are set out.

.../...

Authorities within the Member States in charge of enforcing the main principles of health care: where the aim is to guarantee: healthcare quality and security, access to clear, precise information, the obligation to respond to any harm that may occur during healthcare and non-discrimination between national and overseas patients.

Using healthcare services in another Member State: this chapter sets down the rights of patients to receive healthcare in another Member State and the limits that States can put on healthcare overseas.

Cooperation in different fields of healthcare: this lays down the duty to co-operate in areas such as: recognising prescriptions written in another Member State, developing focal point networks and electronic health programmes, evaluation of health technology and data collection.

Provisions for putting everything into practice and final remarks: here isues relating to the application and coming into force of the Directive are dealt with.

As far as scope of application goes, the Directive shall be applied to healthcare provision independently of the way in which said healthcare is organized, delivered and financed and whether it be public or private.

b) Articles of the treaty providing the basis for the document

The draft Directive is based upon Article 95 of the EU treaty on the establishing and functioning of the internal market and is governed by Article 251 of the EU Treaty on the procedure for joint decision.

The Directive aims to establish freedom of movement for healthcare, since it is considered an economic activity and in this regard follows the rulings of the European Court of Justice. These rulings, regarding the freedom of movement of health services, consider said services as an economic activity subject to Community law.

Equally, several decisions from the European Court of Justice confirm that EU citizens can receive healthcare in a different Member State to theirs and that it shall be the latter that shall cover treatment cost.

This Health Commission, in honouring the principles of subsidiarity and proportionality, considers that the European Commission, by regulating in depth some of the draft's aspects, may have abused its authority with regard to the aforementioned principles which should govern the adoption of legislative measures by the Union's competent authorities.

Having read the draft we can see that it concentrates especially on freedom of movement for patients and does not provide much information on freedom of movement for healthcare services. We should remember that both jurisprudence and current practices in the internal market regulate freedom of movement for both healthcare services and patients,

.../...

and as such the intervention of community authorities, although necessary in some aspects, when taking the perspective of the application of subsidiarity and proportionality principles, represents an abuse of authority in some of the matters that it aims to regulate.

In this regard the draft Directive has an important impact on organizing and supplying health services and medical care, something which is exclusively regulated by Member States. What is more, if we examine the internal constitutional structure of the Kingdom of Spain, this power is shared with the autonomous regions. To this end, we should remember that article 152, paragraph 5 of the EU Treaty stipulates that community action in the field of health care, shall fully respect the responsibilities of Member States in the matter of organizing and supplying health services and medical care.

c) Is the proposed measure within the Community's remit? Is this power exclusive to the Community or shared between the Community and Member States?

The Commission bases this draft proposal on Article 95, which deals with the establishment and operation of the internal market and considers this power as shared. And yet, as we have pointed out above, in the field of public health, article 152.5 EUT limits Community authorities' powers.

Having analysed the current situation that will be affected by the intervention of Community authorities with this proposal, both from the viewpoint of the internal market regarding freedom of movement of healthcare and patients and from the viewpoint of the organization and provision of said healthcare and medical care, even though it is a shared power (with the aforementioned limits), this Health Commission considers that as the draft proposal is written, it may be affecting a field which EU Member States have reserved power over, which would have an impact on the correct, ordered provision of healthcare by the Member States and in our case, on the healthcare provided by the Basque Autonomous Region.

Domestically, Article 149.1.16 of the Spanish Constitution stipulates that the State has exclusive powers over external health, general health co-ordination and the legislation of pharmaceutical products.

Article 18 of the Basque Country's Statute of Autonomy confers on the Basque Autonomous Region, the implementation, execution and management of basic State legislation in the field of internal health and social security and also the execution of State legislation on pharmaceutical products. Similarly, it is stipulated that the Basque Autonomous Commuity can organize and administer within its territory (to the ends explained above) all those services related to the matters expressed above and shall exercise guardianship of the institutions, organizations and foundations providing healthcare and social security, with the State having the task of inspecting to make sure that the functions and remit contained in said article of the Statute of Autonomy are complied with.

.../...

What is more, Law 16/2003 on cohesion and quality in the National Health Service, from the perspective of laying down foundations in health matters, regulates some of the most relevant aspects that appear in the draft Directive.

So, bearing in mind existing legislation and Spain's domestic system for distributing powers, the content of the draft Directive may clash with the *conferral of powers* principal of Member States in public health and also with the exercising of power that corresponds to this Autonomous Region. What is more EU authorities are intervening in aspects that are already regulated by Spain's domestic legislation.

2. Subsidiarity principle

Should the measure be taken at a European level because:

a) *This kind of action is imposed when the objectives of the draft cannot be sufficiently achieved by Member States (whether that be done at a central, regional or local level)?*
and when

b) *This kind of action would have obvious advantages because of the far-reaching nature of its effect?*

The regulation of matters relating to cooperation between States in healthcare and even minimum quality and security guarantees which all European health services should provide so as not to discriminate any citizen, are measures that should be taken at a European level. However, some of the contents of the draft Directive may violate the subsidiarity principle and the conferral of powers in the area of public health in that they may condition the organization of Member States' health systems and overstep the limit of Article 152.2 EUT.

In principle, the way the internal market is currently regulated, jurisprudence from the European Court of Justice and the measures taken by Member States, should be sufficient and should not distort the single market, even though, as has already been explained, part of the proposed objectives can only be achieved if they are carried out at a community level.

Although the measure that has been chosen is a Directive, which gives States a fair margin when it is being transposed to state legislation, nevertheless, the way it is currently worded, if it is taken from the perspective of subsidiarity, may affect the power that article 152.5 EUT reserves for Member States.

3. Proportionality principle

a) *Do the measures proposed go further than is n ecessary to satisfactorialy achieve the objective?*

.../...

b) *If it is thought that the proposed measures do go further than is necessary, what, less restictive action, might be taken to achieve the objective being searched for?*

The measures proposed by the Directive, despite their commendable aim and their desire to provide the application of patients rights in cross-border healthcare with some homogeneity, are not always in keeping with the objectives that really ought to be regulated, since some of their sections penetrate the area reserved for Member States regarding the organization and provision of health services and medical care and in our case have a decisive effect on the Basque Autonomous Region because of the internal distribution of powers already mentioned in Section 1 of this reply.

The impact that the proposed measures may have on the organization of healthcare in Spain and consequently on the Basque Autonomous Community could affect the financial flows of the "Cohesion Fund" and in our case the quota system of our Economic Agreement.

Free movement of health services within the internal market is protected both by community legislation and the decisions taken by the European Court of Justice. What is more, the aim of safe, quality and efficient healthcare is already sufficiently guaranteed by national legislation and by the regulations of the Basque Autonomous Region, with there being sufficient procedures for providing healthcare outside the Basque health system for those citizens who require it.

4. Financial and/or administrative burden

It is not possible to estimate the financial and administrative burden that this Directive would have on healthcare provision in the Basque Autonomous Region, although it is evident that its application would have repercussions in the planning and budgeting of health resources in which population variables are extremely important.

5. Local and regional aspects and how they should be considered in consulting and analysing the impact

a) *Has a full impact assessment been carried out, considering regional and local aspects?*

b) *Have local and regional communities been fully consulted before this draft was adopted?*

The Basque Parliament has been neither consulted nor has it participated in the preparation and writing of this draft Directive, except in this reply which is part of the pilot test of the network of subsidiarity control (third test promoted by the Committee of the Regions)

.../...

6. Quality of the arguments put forward

¿Does the draft provide explicit, sufficient and convincing arguments to show that it fully respects the principles of subsidiarity and proportionality?

As we have alredy said, the Community has taken the simplest form of action possible, a Directive in a field of shared competences, and so the arguments presented try to justify that the conditions established by the subsidiarity and proportionality principles are respected. However, trying to legislate in detail the procedure for providing healthcare to crossborder patients, may go head-to-head in some aspects with the limits of article 152 of the Treaty.

Additional remarks

A regional and local perspective is missing from the impact assessment as well as an independent assessment of subsidiarity and proportioanality that takes into account local and regional authorities with powers in healthcare, as is the case of the Basque Autonomous Region.

.../...

Name of the Authority:	Basque Government
Primary contact person:	Eusko Jaurlaritza
Title of document:	
Reference: **(e.g. COM(2005)112)**	

Proposal for a Directive on the application of patients' rights in cross-border healthcare

1. Legal basis & type of competence:

a) Objective(s) of the document.

b) On which Treaty article(s) is the document based? If you consider the legal basis inappropriate, please give reasons.

c) Does the proposed action fall within the European Community's competences? Is such competence exclusive or shared between the EU and the Member States[8]?

a) Objective(s) of the document.

The proposal for a Directive on the application of patients' rights in cross-border healthcare seeks to establish a clear community framework for cross-border healthcare, which is to be safe, of great quality and efficient. It likewise has to eliminate the barriers to the free movement of patients. It specifically seeks 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 guaranteed for cross-border care. This is structured around three main areas:

Common principles in all EU health systems: in order to ensure that there is clarity and confidence regarding the healthcare provided, access of patients to clear and precise information, the obligation to ensure appropriate remedies and compensation for harm arising from healthcare, and the non-discrimination between patients of the country where the treatment is provided and foreign patients;

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. Therefore, the insured individuals who have received care in another Member State shall be reimbursed provided that the treatment is within the services covered by the legislation of the Member State of affiliation to which the insured individual is entitled. The Member State of affiliation may likewise lay down for the patient seeking healthcare in another State the same conditions, criteria of eligibility and regulatory and administrative formalities to receive that care

[8] If the competence is exclusive, the subsidiarity principle does not apply. If this is the case, please go directly to the proportionality section of this questionnaire.

and for the reimbursement of the ensuing costs that would have applied in its country, provided that they are non-discriminatory and do not hinder the free movement of people;

European Cooperation on healthcare: which will be underpinned by partnership between countries, the recognition of prescriptions issued in other Member States, data collection for statistical purposes, the development of European referral networks and cooperation in electronic health.

With respect to the **scope of application**, the Directive shall apply to the provision of healthcare regardless of how it is organised, delivered and financed or whether it is public or private.

b) On which Treaty article(s) is the document based? If you consider the legal basis inappropriate, please give reasons.

The proposal for a Directive is based on Article 95 of the EC Treaty concerning the establishment and functioning of the internal market and is governed by Article 251 of the EC Treaty referring to the co-decision procedure. The Directive seeks to guarantee the free movement of health services and health services are an economic activity. That has been established in the case law of the European Court of Justice, whose judgements regarding the application of the principles of free movement to health services show that they must be considered as an economic activity to which community law applies.

These judgements[9] confirm that EU citizens may receive healthcare in a different Member State to the State of the affiliation, with the latter covering the treatment. Such situations occur when the medical care is better provided in another Member State, for example, in the case of rare diseases or specialised treatment, and also when the nearest centre is located in another State in cross-border regions.

Even though case law regards health services as an economic activity, healthcare was excluded from the sphere of application of Directive 2006/123/CE[10] concerning services in the internal market. The institutions therefore wanted to tackle that matter in a specific juridical instrument of the European Community, in order to achieve a more general and efficient application of the principles developed case by case by the Court of Justice regarding cross-border healthcare. This Proposal for a Directive on the application of patients' rights in cross-border healthcare has therefore been drafted and its legal base is Article 95 of the EC Treaty.

The European Commission's justification that the objective of the Directive to guarantee the free circulation of the health services in the internal is in keeping with the requirement of Article 95 of the EC Treaty is not appropriate in reality and according to our analysis. The legal grounds are not appropriate as this Directive does not contribute anything to the free movement of health services and

[9] Judgements in C-158/96 Kohll, Rec. 1998, p. I-1931; C-120/95 Decker, Rec. 1998, p. I-1831; C-368/98 Vanbraekel, Rec. 2001, p. I-5363; C-157/99 Smits & Peerbooms, Rec. 2001, p. I-5473; C-56/01 Inizan, Rec. 2003, p. I-12403; C-8/02 Leichtle, Rec. 2004, p. I-2641; y C-385/99 Müller-Fauré & Van Riet, Rec. 2003, p. I-4503; together with the judgement in C-372/04 Watts, Rec. 2006, p. I-4325.

[10] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006L0123:ES:HTML

is particularly focused on the free movement of patients. Not only that, the Directive also has a significant impact on the organisation and supply of health services and medical care, a competence that is exclusively of the Member States, and where applicable, of the regions.

First of all, the judgements, the case law and the existing practice in the internal market already sufficiently regulate the free movement of health services, along with the mobility of the patients. The Directive therefore does not contribute to the achievement of the free movement of health services and infringes the principle of subsidiarity as the intervention of the EU in this case is unnecessary.

Secondly, the Directive does not take into account the principle of conferral of competences to the Member States in the health field. Article 152 (5) of the EC Treaty, establishes that the community action in the public health sphere shall fully respect the responsibilities of the Member States regarding the organisation and supply of health services and medical care. However, this Directive so infringes on the organisation and the provision of health services, the expressly reserved competences of the EU Member States, that it is a breach of the principle of subsidiarity and principle of conferral of competences.

In conclusion, on the one hand, it breaches the principle of subsidiarity as this Directive does not specifically favour the free movement of health services. On the other hand, it is a conferral of competences to the EU in an area such as public health, where the legislative competence is exclusively reserved for the Member States and, in our case, to the Autonomous Communities (regions).

We therefore wish to stress that the health systems are the responsibility of the Member States and it is these, and in our case the Autonomous Communities, which organise and provide the health services and medical care in their territories. We therefore consider that the proposal for a Directive is in breach of the competences of the Member States to organise their health services as they so wish.

c) Does the proposed action fall within the European Community's competences?

Starting with the internal market, the proposed measures does not tally with the competences of the Community as the current legislation on the internal market and the precedent case law already guarantees the free movement of health services. This proposal for a Directive is therefore abusing the competence of the Community to intervene in an area where there is no need to legislate.

On other hand, as far as public health is concerned, and has been already stated, this Directive goes far beyond the elimination of the obstacles to the free movement of the patients and the health services as it is in breach of the exclusive competences of the Member States of health matters and, in our case, of the Autonomous Community of the Basque Country, which is responsible for organising and providing the health services and medical care. In our opinion, the impact of this Directive on the organisation and provision of health services would be significant and negative and would encroach on the competences of the Member States.

Is such competence exclusive or shared between the EU and the Member States[11]?

The Commission bases the proposal on Article 95 concerning the establishment and functioning of the internal market, as, even though that competence is shared between the EU and the Member States, EU legislative activity has been so far-reaching in the sphere of the internal market that the EU has assumed a more important role than the Member States. Thus, using the principle of subsidiarity in favour of EU competences, the EU has legislated a great deal on internal market policy and has taken on a leadership role by turning shared competence into something exclusive. This is the case of this proposal for a Directive that is not only not necessary but also leads to a dysfunctional system.

As far as public health is concerned, this area is the exclusive competence of the Member States, as laid down in Article 152.5 of the EC Treaty. However, the EU, with this proposal for a Directive, is in breach of the principle of conferral of competences as it is does not take into consideration the ensuring consequences regarding the organisation and provision of health services and medical care, a competence that, undoubtedly, is held by the Member States and, in our case, the Autonomous Communities (regions).

It should be first pointed out that, pursuant to Article 149.1.16 of the Spanish Constitution, the Spanish State has exclusive competence in the area of external health measures, basic conditions and general coordination of health matters and legislation on pharmaceutical products. It is important to point out that Constitutional Court Judgement (STC) 42/1983, of 20 May, determined that the State had competence over the fundaments (minimum regulatory contents), general coordination and overall inspection in health matters.

Article 18 of the **Statute of Autonomy of the Basque Country (Estatuto de Gernika)** entrusts to the Autonomous Community of the Basque Country the legislative development and the implementation of the basic legislation of the State in matters of domestic health, the legislative development and the execution of basic State legislation in Social Security matters (except the rules which govern the economic organisation of the Social Security), together with its management and, finally, the execution of State legislation on pharmaceutical products. Section 4 of said Article 18 establishes that the **Autonomous Community of the Basque Country may organize and administer**, for these purposes, a**nd within its own territory**, **all the services connected with the matters previously expressed and shall supervise institutions, organizations and foundations as regards Health and Social Security matters**. The State shall keep for itself the inspection powers so as to ensure the fulfilment of the duties and powers contained in this Article 19 of the Statute.

As far as the Provincial Councils are concerned, Act 27/1983, of 25 November, concerning Relations between the Common Institutions of the Autonomous Community and the Provincial Entities of the Historical Territories (Historical Territories Act) did not reserve any competence in the field of healthcare for the provincial institutions. In principle, that places these institutions outside the regulation contained in the proposal for a Directive relating to the application of patient rights in

[11] If the competence is exclusive, the subsidiarity principle does not apply. If this is the case, please go directly to the proportionality section of this questionnaire.

cross-border healthcare, as the field of social care where there could be the strongest link with the purpose of the Directive (Article 7 LTH) is excluded from the Directive.

Therefore, bearing in this mind this competence distribution system where the Autonomous Community of the Basque Country is responsible for organising and providing health services and medical care, the contents envisaged in the proposal for a Directive encroach on that competence: This encroachment is set out in the following paragraphs:

- As far as the responsibilities of the Member State of treatment are concerned, in Article 4 of the Directive, these responsibilities are basically laid down as the organisation and delivery of healthcare, in other words, what, where applicable, should be provided by the health services of the Autonomous Communities. At an internal level (Spanish State), this is a requirement for the competent Autonomous Communities that when they act as a member state of treatment, they have the necessary resources and measures to check the compliance of the requirements envisaged in said Article 5, irrespective of the fact that it is up to the State to establish the bases for healthcare (General Health Act 14/1986, of 29 April, and National Health System Quality and Cohesion Act 16/2003, of 28 of May).

- With regard to Article 6 of Directive concerning the healthcare provided in another Member State, irrespective of the bases established for the State, the Autonomous Communities, such as the Basque Country, with legislative development and execution competences have a role to play in this area. The same can be said about Article 7 of the Directive with respect to non-hospital care.

- Similar comments have to be made about Article 8 regarding hospital and specialised care and prior authorisation. In other words, irrespective of the fact that it is up to the State to establish the bases, i.e., the minimum healthcare regulatory contents, the Autonomous Communities, in addition to executing those bases, are legally empowered to develop them.

- The same can be said of Articles 9, 10 and 12. The procedural guarantees of Article 9, the need to provide information to patients envisaged in Article 10 and the designation of healthcare contact points of Article 12, are instrumental aspects that go hand in hand with the exercising of an material implementation and, as such, aspects of the competence of the health services of the Autonomous Communities.

- It is the healthcare cooperation established by the Directive where the intervention of different territorial levels is of greatest importance. Article 13 expressly establishes this when it refers to local and regional levels in the framework of the use of information and communication technologies to provide cross-frontier healthcare.

- The participation of the Autonomous Communities is also necessary in the European referral networks referred to in Article 15, as their objectives are basic and of particular interest for any territorial entity that has competences in the health field.

.../...

- Article 16 regarding E-health, Article 17 concerning cooperation on management of new health technologies and Article 18 regarding data collection for statistical and monitoring purposes are also in the sphere of the competences of the Autonomous Communities, which is clear in the case of the exclusive statistics and in that of cooperation when it necessarily refers to different levels of territorial competences.

Article 25 of the Local Government Act considers the protection of public health (h) and the participation in the management of primary healthcare (i) as the competence of the municipalities, in terms of the legislation of the State and of the Autonomous Communities. The participation of other territorial authorities, apart from the State and autonomous ones, in the management and checking of the contents of the proposal for a Directive cannot be overlook, at least with respect to the cooperation mechanisms, as is the requirement of the community regulation and current internal legislation.

On the other hand, the National Health System Quality and Cohesion Act 16/2003 is the legislation that regulates, at State level, some of the most important aspects included in the proposal for a Directive from the perspectives of establishing the healthcare bases. Its Article 3.1b) (Act 16/2003) establishes that the nationals of EU Member States have the rights resulting from European community law and the treaties and conventions signed by the Spanish States and others of application. In other words, part of the regulation set out in the proposal for a Directive is already included at an internal level. Other matters dealt with in the Directive and already envisaged in the aforementioned legislation relate to the health information system (Article 53), the communications network of the National Health System (Article 54) and the regulation of supracommunity statistics of general interest (Article 55), where Act 16/2003 attributes the leadership to the Ministry of Health and Consumers, without prejudice to the necessary participation of these purposes of the competent Autonomous Communities in the health field. The Act likewise considers the so-called "Cohesion Fund" in the 5th addendum, whose purpose is to guarantee equal access to public healthcare services throughout Spanish territory and care for citizens in Spain from other countries of the EU or from countries with a reciprocal healthcare agreement with Spain, which shall be managed by the Ministry for Health and Consumers.

In conclusion, on the one hand, the principle of conferral of competences of the Member State in public health is breached, because the Directive encroaches on this competence and, on the other hand, the Community unnecessarily intervenes with a Directive that does not help to improve the health services and which includes already regulated aspects, as can be seen from Act 16/2003.

2. Subsidiarity principle

Should action be taken at European level, because:

(a) such action is necessary insofar as the Member States (either at the central or at regional and local levels) cannot sufficiently achieve the objective of the proposed measure,

and

(b) such action would have a clear benefit by reason of its scale or effects?

As has been previously stated, the objective of the proposal for a Directive is to establish a general framework for the provision of safe, high quality and efficient cross-border healthcare. The Directive is divided into 4 main areas (chapters):

.../...

General provisions: where it is established that the sphere of application shall be the provision of healthcare regardless of how it is organised, delivered and financed or whether it is public or private.

Common principles: which seeks to ensure that there is clarity and confidence regarding the health care provided, access of patients to clear and precise information, the obligation to ensure appropriate remedies and compensation for harm arising from healthcare, and the non-discrimination between patients of the country of origin and foreign patients;

Use of the healthcare in another Member State: it sets out the right of patients to receive health care in another Member States and the limits that the States may establish on that healthcare abroad.

Healthcare cooperation: it establishes the duty to cooperate in the recognition of prescriptions issued in another Member States, in the development of referral centre networks, in the development of E-health projects, in the assessment of health technologies and in the collection of statistical data.

In our opinion, European regulation regarding areas of cooperation between States on health issues and even the minimum quality and safety guarantees that all European health system must provide to ensure there is no discrimination of any citizen, are measures that can be taken at a European level. They may even include other areas that the rights and duties of the citizens are broadly regulated in terms of healthcare.

Yet the proposed Directive focuses particularly on the free movement of patients without taking into account the ensuing consequences on the very organisation of the health systems, which is the exclusive competence of the Autonomous Communities and, therefore, breaches the principle of conferral of competences.

This principle of free movement of patients is not recognised in the Basque health system, but is conditional on a health organisation (basic health zones, referral specialists, etc.) requiring the appropriate administrative authorisations to request medical care outside these spheres. These restrictions on mobility, which are necessary, proportionate and non-discriminatory, would not (according to the Directive) necessary to provide non-hospital healthcare.

The Directive defined non-hospital healthcare and hospital healthcare, which it differentiates according to whether or not the patient needs to be admitted for at least one night. This is an arbitrary differentiation that does not take into account the organisation of the provision of health care in our health system and attributes to the European Commission the competence to prepare and update a list of what is to be taken to be hospital healthcare.

Furthermore, the Directive would apply to the public and private sector, but does not regulate how it would affect each of the spheres and does not specify if healthcare could be requested in either sector or if one or other network could even be chosen within the same country. The lack of definition could be highly detrimental to public healthcare and boost private healthcare.

In conclusion, this Directive would not contribute anything that is not regulated in the sphere of the Basque public health system, as we already have legislation that guarantees timely healthcare (Waiting List Decree) and the channel is established to request healthcare outside our health system and the reimbursement mechanism should that care be provided. It would not provide anything new to the free movement of patients in the internal market, which means that the quality of cross-border health care would not improve. The Directive would therefore be in breach of the principle of subsidiarity.

3. Proportionality principle:

a) Do the proposed measures go beyond what is necessary to satisfactorily achieve the intended objectives?

b) If you consider that the proposed measures indeed go further than what is necessary, what would you consider to be a less restrictive, alternative way to achieve the intended objectives?

The measures proposed in the Directive go far beyond the elimination of the obstacles to the free movement of the patients and the health services as it is in breach of the exclusive competences of the Member States of health matters and, in our case, of the Autonomous Community of the Basque Country, which is responsible for organising and providing the health services and medical care. Current internal market legislation and case law already guarantees the free movement of health services.

The number of citizens that would be affected by this Directive (which the European Commission itself estimates to be around 2%, a figure that would be even lower in the Basque Health system) barely even starts to justify a Directive that would have a great impact on the healthcare organisational system in our country (in the Autonomous Community of the Basque Country) and on the cash flow model.

This Directive could affect Spanish social security legislation and the aforementioned healthcare legislation (National Health System Quality and Cohesion Act 16/2003), together with the management of the "Cohesion Fund", conditional in turn on the financial model between the Autonomous Community of the Basque Country and the Spanish State.

The objectives of safe, high quality and efficient healthcare are already duly guaranteed by the legislation of the Autonomous Community and there is a sufficient procedure to provide the necessary healthcare outside the sphere of our own Basque health system for those citizens that require it.

Citizens residing near to the borders between different Member States could benefit from better healthcare access thanks to cooperation agreements between the healthcare providers, without any need to resort to a Directive such as the one proposed.

4. Financial and/or administrative burden:

a) Please indicate whether the financial and/or administrative burden falling upon the European Community, national governments, regional and local authorities, economic operators and citizens is commensurate to the objectives of the proposal and whether it has been kept to an absolute minimum.

.../...

It has been possible to calculate the administrative and financial burden that this Directive would have on the Basque health system.

Unquestionably, the strict attempt to safeguard the freedom of movement among European citizens, could be an incentive for the reviled "health tourism"; with a negative impact on the planning and budgeting of the health resources where the population variable is of key importance.

This Directive could also lead to citizens' requesting unjustified "second medical opinions" at a considerable financial cost.

5. Consideration of local and regional factors in the impact assessment and consultation

a) Has a comprehensive impact assessment been presented, which takes into account local and regional aspects?

b) Have local and regional authorities been adequately consulted prior to the adoption of the proposal? In case you have participated in such a consultation, please specify the practical details of your participation and provide an assessment of your experience.

There has been no participation so far in the preparing and drawing up of this Directive.

The Spanish Ministry of Health and Consumers has expressed its intention to consult the Autonomous Community of the Basque Country and the other Autonomous Communities to take a common stand to defend the overall interests of the National Health System.

6. Quality of the arguments provided:

a) Does the proposal provide clear, adequate and convincing arguments to justify its compliance with the subsidiarity and proportionality principles?

b) Are these arguments based on qualitative as well as quantitative indicators?

The Directive seeks to justify safeguarding the responsibility of the Member States in the organisation and provision of sanitary services, even when establishing the regulations to be applied to reimburse the patients. However, it attempts to legislate in detail on the procedure to assume cross-border healthcare, which, *de facto*, interferes in the competences referring to the organisation of the health services themselves and breaches the principle of subsidiarity and the principle of conferral of competences.

The legislator justifies the need for the Directive by arguing that there is an alleged risk to achieving a high risk of health protection, an alleged uncertainty about the application of the right to reimbursement for healthcare provided in another Member State, the lack of mechanisms that

.../...

guarantee the quality and safety of the healthcare provided or the difficulty for the continuity of care among the different healthcare workers and organisations treating the patient.

Further comments

There are other observations that must be made regarding the Directive, such as the proposed procedure for prescribing pharmaceutical products and the practical difficulty in implementing it due to the different community languages, the lack of definition between non-hospital care and hospital care, which leaves the definition at any given time of what is included in each of them to the whim of the European Commission or the risk that this Directive may tend to foster *de facto* private health care over fair and universal public health care.

Name of the Authority:	Assemblea legislativa della Regione Emilia-Romagna
Primary contact person:	Anna Voltan
Title of document:	Proposal for a Directive of the European Parliament and of the Council on the application of patient's rights in cross-border healthcare
Reference: **(e.g. COM(2005)112)**	COM (2008) 414

1. Legal basis & type of competence:	
a) Objective(s) of the document.	a) The main objective of the proposal is to ensure a legal framework for cross border healthcare within the EU, with the aim of enabling patients to exercise their rights of reimbursement of healthcare provided in another Member State and the free movement of health services whilst ensuring a high level of health protection.
b) On which Treaty article(s) is the document based? If you consider the legal basis inappropriate, please give reasons.	b) The proposal is based on Article 95 ECT which regards measures that have as their object the establishment and functioning of the internal market.
c) Does the proposed action fall within the European Community's competences? Is such competence exclusive or shared between the Community and the Member States[12]?	c) The proposal theoretically falls within the shared competences. Actually, it may be that the action, as proposed, invades MS's exclusive competence in organizing their own health systems. It has to be noted that the proposal also aims at ensuring free movement of health services and a high level of health protection. Therefore, it follows that the proposal is also closely linked to the actions provided by Article 152 ECT in the public health sector, which also falls within the European Community's shared competences. For this aspects also it has to be pointed out the risk to invade exclusive competences of the MSs.

2. Subsidiarity principle	
Should action be taken at European level, because (a) such action is necessary insofar as the Member	a) The addressed issue has clearly transnational

[12] If the competence is exclusive, the subsidiarity principle does not apply. If this is the case, please go directly to the proportionality section of this questionnaire.

.../...

States (either at the central or at regional and local levels) cannot sufficiently achieve the objective of the proposed measure, and (b) such action would have a clear benefit by reason of its scale or effects? Please provide a reasoned answer to the above question while giving consideration to the following: i) whether the issue being addressed has trans-national aspects that cannot be properly regulated by action of Member States and/ or their local and regional authorities; ii) whether action by Member States alone would conflict with the requirements of the Treaty or would otherwise significantly damage the Member States' interests; iii) whether existing Community measures or targeted assistance provided hereunder would be sufficient to achieve the intended objectives.	relevance and Member States alone, at national and regional level, cannot provide for a clear legal framework. As far as cooperation, exchange of information, networks are concerned, an action at national level would not be suitable to achieve the objective of the proposal. b) Advantages, as a result of the proposed action, can be identified in the wider possibility to access to health services for all European citizens. However, this could be an advantage only on a theoretical point of view. Indeed, it is not possible at the moment to verify what the real impact will be on the National Health Systems and on the Regional Health System in Emilia – Romagna, as a consequence of the implementation of the proposed Directive.

3. Proportionality principle: a) Do the proposed measures go beyond what is necessary to satisfactorily achieve the intended objectives? Please provide a reasoned answer while giving consideration to the following elements: i) whether the proposed form of action is as straightforward as possible (for example directives should be preferred to regulations and framework directives to detailed measures). ii) whether the proposed action leaves as much room for national decision as possible. iii) whether the proposed measures take account of well established national arrangements and special circumstances applying in your Member State or region (e.g. the organisation and functioning of the legal system).	a) As far as the form of action, the directive is theoretically the more suitable instrument to leave a margin of manoeuvre to the Member States which should pass enacting measures taking into account the domestic healthcare organization and the programmatic and organizing choices made according to their related exclusive competence. Moreover, several points of the proposal provide for the accomplishment at EU level – according to the comitology mechanism – of the aspects which may have a significant impact on the healthcare systems at different levels (national and regional).

.../...

b) If you consider that the proposed measures indeed go further than what is necessary, what would you consider to be a less restrictive, alternative way to achieve the intended objectives?	

4. Financial and/or administrative burden: a) Please indicate whether the financial and/or administrative burden falling upon the European Community, national governments, regional and local authorities, economic operators and citizens is commensurate to the objectives of the proposal and whether it has been kept to an absolute minimum. b) If the relevant data is available to you, please provide an estimation of the financial and/ or administrative burden the implementation of the present proposal would entail for your administration and/ or in the territory of your local or regional authority.	a) Currently, we don't have the information needed to exactly assess the financial and administrative burdens that will fall on the regional level of Emilia-Romagna. Therefore we can't provide an exact assessment of their proportionality in relation to the objectives.

Better Regulation & Preparation of the proposal	
5. Consideration of local and regional factors in the impact assessment and consultation a) Has a comprehensive impact assessment been presented, which takes into account local and regional aspects?	a) Yes, an impact assessment report has been presented, avalaible in English. In preparing the impact assessment report local and regional data were used. (see "International comparison of costs: An exploration of within and between country variations for ten healthcare services in nine EU member states", project coordinated by European Health Management Association EHMA). However, despite the use of local and regional data, the analysis of policy options has been conducted at EU level, as far as the same analysis can't be detailed for each region.
b) Have local and regional authorities been adequately consulted prior to the adoption of the proposal? In case you have participated in such a consultation, please specify the practical details of your participation	b) The Commission has carried out a wide public consultation (since September 2006) as provided for adoption of relevant proposal.

.../...

and provide an assessment of your experience.	
6. Quality of the arguments provided: a) Does the proposal provide clear, adequate and convincing arguments to justify its compliance with the subsidiarity and proportionality principles?	a) The proposal provides arguments to justify its compliance with the subsidiarity and proportionality principles. Indeed, the policy options have been identified in compliance with the European Court of Justice rulings, seeking to establish a general framework that ensures safe, high quality and efficient cross-border healthcare. Impact assessment report analyzes the compliance with the subsidiarity and proportionality principles. Specifically, the policy options analysis is conducted taking into account the compliance with the two principles. For example, already in prior analysis of option 4 (rejected option that provided for the adoption of detailed legal rules established at European level) the difficulty to justify its adoption in the light of the subsidiarity principle was highlighted.
b) Are these arguments based on qualitative as well as quantitative indicators?	b) The arguments provided in the report accompanying the proposal are based on qualitative indicators. The policy options analysis carried out in the impact assessment report is based both on qualitative and quantitative indicators. Indeed, the comparison of policy options is based on quantitative impacts (in financial terms) as well as qualitative (i.e. patients' satisfaction).
Further comments Please feel free to provide additional feedback on the overall quality of the proposal, i.e. clarity of drafting, simplicity of implementation at the regional and local level, need for a more thorough debate within the course of the legislative process on the financial/ and or administrative burden the proposal would entail, suitability of the envisaged action with regard to the intended objectives etc.	Further comments: - As a consequence of the adoption of the directive, a problematic economic and financial impact on national and regional health systems, on their programming and the actual way of access to the healthcare provision, may be caused. The MSs are now gradually converging towards

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	principles and proceedings in adopting the rules and action plans of the respective national health systems. This process could not take advantage from the risk of absence of control and limits, the free of choice, as well as the reimbursement of cross border healthcare. - Burdens in adopting new organization instruments and regulations will derive for MSs and Regions that will provide for the implementation of the directive. New rules of proceedings, new organizational patterns and information systems will be set up by MSs and Regions implementing the directive as far as their respective health systems are concerned (Articles 6, 8, 9, 10, 11 of the proposal). A much more long term for implementation should be provided (Article 22 of the proposal). - A political position of the Italian Regions on this proposal for a Directive is currently under discussion within the Italian Conference of the Regions. Emilia – Romagna is now involved in this political process that would hopefully take to a united and shared regional position. - The proposal affects a framework that shows at that time several elements of unhomogeneity within the different systems of the MSs which concern the organization and the offer of health services. This situation already causes an imbalance of the offer of services which may further deteriorate. This would make the existing elements of inequality and inequity concerning the access to health services by EU citizens worse. - A further problematic point of the proposal is represented by the necessity to clarify the principle by which the patients can have healthcare in another MS and reimbursement from the MS of affiliation of the costs which would have been paid for by its statutory social security system (Article 6 of the proposal). Indeed, it should be pointed the existence of strong differences in relation to the identification of standards and kind of healthcare services provided by the MSs and also as far as the specification of the criteria for

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	receiving healthcare and reimbursement of healthcare costs is concerned. - The proposal (Articles 7 and 8) does not make clear the possibility to take into account sanitary criteria in order to provide high quality of healthcare services within the system of prior authorisation. - Finally the system of recognitions of the subscriptions issued in another MS seems problematic (Article 14 of the proposal). Indeed, this system runs the risk of invalidating the in progress national and regional policies on the use and reimbursement of drugs.

Name of the Authority:	Regional Council of Tuscany – ***Special Commission for Relations with the European Union and International Relations of the Region***
Primary contact person:	***Fiamma Zambrini***
Title of document:	**Proposal for a Directive on the application of patients' rights in cross-border healthcare**
Reference: **(e.g. COM(2005) 112)**	**COM(2008) 414 final**

1. Legal basis & type of competence:	
a) Objective(s) of the document.	a) The objective of the document is to provide a clear framework governing cross-border healthcare. It would put in place an alternative mechanism to the existing regulatory framework, 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 States that they would have been provided at home and be reimbursed up to the amount that they would have been paid had they obtained that treatment at home, but they bear the financial risk of any additional costs arising.
b) On which Treaty article(s) is the document based? If you consider the legal basis inappropriate, please give reasons.	b) Healthcare constitutes a "service" under the terms of Article 50 of the EC Treaty (ECT). Consequently, measures to establish an internal market in cross-border healthcare must be taken under Article 95 of the EC Treaty. It should however be noted that measures taken on this legal basis must provide a high level of health protection (Article 95(3) ECT), which must at the same time be ensured in the definition and implementation of all Community policies and actions (Article 152(1) ECT).
c) Does the proposed action fall within the European Community's competences? Is such competence exclusive or shared between the Community and the Member States[13]?	c) Both free movement of services and healthcare are areas that are shared competences of the Community. The principles of subsidiarity and proportionality are therefore both relevant for assessing legislative

[13] If the competence is exclusive, the subsidiarity principle does not apply. If this is the case, please go directly to the proportionality section of this questionnaire.

	proposals in these sectors.

2. Subsidiarity principle Should action be taken at European level, because a) such action is necessary insofar as the Member States (either at the central or at regional and local levels) cannot sufficiently achieve the objective of the proposed measure, and b) such action would have a clear benefit by reason of its scale or effects? Please provide a reasoned answer to the above question while giving consideration to the following: i) whether the issue being addressed has trans-	a) Achieving the internal market and clearly establishing patients' entitlement to reimbursement of healthcare obtained in another Member State are not matters that can be left by the Member States alone or their local and regional authorities. b) By its very nature, cross-border healthcare have trans-national aspects (most obviously in frontier and remote regions), and the Member States are not in a position to deal satisfactorily with the resulting challenges. The directive does not question the way the Member States and, where appropriate, their regional or local authorities choose to organise their health systems and medical care (Article 152(5) ECT). It does not affect the right of Member States to define the healthcare benefits that they choose to provide under their healthcare systems, nor does it create an automatic right for patients to seek treatment abroad when these are not provided by the Member State of affiliation. However, the Commission concedes that application of the directive may be such that the Member States are required to make adjustments to their national health and social security systems, but does not consider that such an eventuality would undermine their sovereign powers in the field of healthcare. A question may arise concerning the way the Member

national aspects that cannot be properly regulated by action of Member States and/ or their local and regional authorities; ii) whether action by Member States alone would conflict with the requirements of the Treaty or would otherwise significantly damage the Member States' interests; iii) whether existing Community measures or targeted assistance provided hereunder would be sufficient to achieve the intended objectives.	States assume their responsibility for treatment provided on their territory in accordance with the principles of universality, access to good quality healthcare, equity and solidarity. Article 5 of the draft directive provides that the Member States must define quality and safety standards for healthcare, and lists the factors that must be taken into account when defining such standards. It is considered that the existence of these standards should not affect Member States' powers in the health field, even if the way they may be established (guidelines drawn up by the Commission with the cooperation of the Member States) might be open to criticism.

3. Proportionality principle: a) Do the proposed measures go beyond what is necessary to satisfactorily achieve the intended objectives? Please provide a reasoned answer while giving consideration to the following elements: i) whether the proposed form of action is as straightforward as possible (for example directives should be preferred to regulations and framework directives to detailed measures). ii) whether the proposed action leaves as much room for national decision as possible. iii) whether the proposed measures take account of well established national arrangements and special circumstances applying in your Member State or region (e.g. the organisation and functioning of the legal system). b) If you consider that the proposed measures indeed go further than what is necessary, what would you consider to be a less restrictive, alternative way to achieve the intended objectives?	a) It is argued that the draft proposal under discussion simply formulates general principles, leaving a wide margin to the members regarding implementation in accordance with national, regional and local circumstances. It is also claimed that the proposal respects the organisation of the health system and medical care of the Member States (Article 152(3) ECT). In spite of the above, however, the draft proposal may be considered to be likely to provide the Member States and their regional and local authorities with more detailed guidance on the conditions in which they may be entitled to require a prior authorisation for hospital treatment in another country. In view of the fact that one of the objectives of the proposal is to offer both patients and Member States greater clarity concerning the principles laid down in CJEC case-law with regard to the application of patients' rights, Article 8(3) of the proposal may be seen as rather vague. Although the conditions in which a prior authorisation system may be set up are mentioned, nothing is said about the level of proof that Member States and their administrations must provide to justify a system of this type. The explanatory memorandum of the document does explain that the Member States must provide evidence that the conditions justifying the introduction of a prior authorisation system are met, but no further clarification is forthcoming.

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4. Financial and/or administrative burden: a) Please indicate whether the financial and/or administrative burden falling upon the European Community, national governments, regional and local authorities, economic operators and citizens is commensurate to the objectives of the proposal and whether it has been kept to an absolute minimum.	a) With regard to the financial or administrative burden arising from the possible implementation of the draft directive, the Commission maintains that it is unlikely that the impact of cross-border healthcare will cause major changes to health systems as a whole, insofar as it is expected that cross-border healthcare will remain marginal. However, fulfilling the various requirements of the directive (i.e. structures to provide information to patients, introduction of national contact points, measures to ensure interoperability of on-line health services, etc.) will inevitably entail substantial costs for the public authorities concerned, although they are considered to be proportionate to the benefits generated by providing cross-border healthcare.
b) If the relevant data is available to you, please provide an estimation of the financial and/ or administrative burden the implementation of the present proposal would entail for your administration and/ or in the territory of your local or regional authority.	b) The Region of Tuscany does not yet have relevant data with which to estimate the financial and/or administrative burden that the proposal would entail.

Better Regulation & Preparation of the proposal	
5. Consideration of local and regional factors in the impact assessment and consultation a) Has a comprehensive impact assessment been presented, which takes into account local and regional aspects? b) Have local and regional authorities been adequately consulted prior to the adoption of the proposal? In case you have participated in such a consultation, please specify the practical details of your participation and provide an assessment of your experience.	a) It may be noted that the impact assessment presented by the Commission has little to say about the possible territorial consequences of the draft directive. b) It may also be noted that local and regional authorities would have needed closer consultation prior to adoption of the proposal.
6. Quality of the arguments provided: a) Does the proposal provide clear, adequate and convincing arguments to justify its compliance with the subsidiarity and proportionality principles? b) Are these arguments based on qualitative as well as quantitative indicators?	a) The Commission proposes to publish guidelines, in cooperation with the Member States, specifying the quality and safety standards for healthcare provided in the Member States. Such a proposal may be questionable, in that the adoption, in this a way, of guidelines, would be carried out without the

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	involvement of the European Parliament, the Committee of the Regions or the European Economic and Social Committee, who would probably have a valuable contribution to make based on their various areas of expertise. Neither is the status of these guidelines at all clear. Guidelines are by definition legally non-binding, but the present ones are intended to establish quality and safety standards for healthcare in the Member State of treatment and are, therefore, likely to have an impact on the evaluation of a State's responsibility in the event of any appeals to the CJEC, whether infringement proceedings or requests for preliminary rulings.
Further comments Please feel free to provide additional feedback on the overall quality of the proposal, i.e. clarity of drafting, simplicity of implementation at the regional and local level, need for a more thorough debate within the course of the legislative process on the financial/ and or administrative burden the proposal would entail, suitability of the envisaged action with regard to the intended objectives etc.	Uncertainty remains, especially at regional level, concerning the scope of prior authorisation, and the precise outlines of this authorisation must be specified. The proposed distinction between hospital and out patient care, which may not require prior authorisation, seems rather obsolete. In practice, apart from the distinction between hospital and non-hospital treatment, account should be taken of the cost of certain techniques, and a list should be drawn up at European level of "particularly costly techniques" requiring prior authorisation, regardless of hospitalisation or otherwise. There could also be a risk that the directive might aggravate health inequalities, since patients will have to pay in advance for treatment received abroad and bear the financial risk of any additional costs arising. Lastly, care must be taken to ensure that the most vulnerable categories of patient are also able to exercise the rights granted to them by Community legislation. This implies that clear information must be available where citizens ask for it.

Regional Executive Committee of Lombardy

Questionnaire responses - already available online at 11.51 a.m. on 17.10.2008 (*full analysis*) – concerning the Proposal for a Directive on the application of patients' rights in cross-border healthcare (COM(2008) 414)

1. Legal basis and type of competence

a) Objective(s) of the proposal

Mainly at the request of the Council of the European Union of 1 and 2 June 2006, the Proposal for a Directive on the Application of Patients' Rights in Cross-border Healthcare seeks to establish a general legal reference framework for cross-border healthcare, whilst ensuring patient mobility and the freedom to provide health services and a minimum high level of health protection.

b) On which Treaty article(s) is the document based? If you consider the legal basis inappropriate, please give reasons

The proposal for a directive is based on Article 95 of the EC Treaty, which seeks to harmonise national measures which could contribute to the establishment and proper functioning of the internal market. The provision of healthcare, as indicated, falls within the scope of the Treaty and, in particular, of measures concerning the freedom to provide services, since it broadly constitutes an economic activity provided for remuneration (*ex multis*, Judgment of the Court of Justice of the European Communities (ECJ), 4 October 1991, *The Society for the Protection of Unborn Children Ireland*, Case C-159/90, point 18; ECJ Judgment, 28 April 1998, Case C-158/96, *Kohll*, point 29). The directive under consideration also falls within the framework of measures that the EU can adopt under Article 152 of the Treaty on public health, for the protection and improvement of human health (see Recital 1 of the proposal).

c) Does the proposed action fall within the European Community's competences? Is such competence exclusive or shared between the Community and the Member States[14]?

The proposed measure is a shared EU-Member State competence, both with respect to the objective of completing the internal market by fully achieving the freedom to provide health services as well as with respect to the specific area of public health. With regard to the latter, Treaty Article 152 explicitly defines Community action as action that "shall complement national policies". On first analysis, the proposal under consideration appears to comply with the principle of subsidiarity implicitly sanctioned in the aforementioned Article 152 and, in general, of the principles of subsidiarity and proportionality, namely Article 5 of the Treaty.

2. The principle of subsidiarity

14 If the competence is exclusive, the subsidiarity principle does not apply. If this is the case, please go directly to the proportionality section of this questionnaire.

Community action is necessary insofar as

(a) the objectives of the proposal cannot be adequately accomplished by the Member States (be it at the national, regional or local level)

and that

(b) such action would have a clear benefit by reason of its scale or effects?

Please provide a reasoned answer to the above question while giving consideration to the following:

i) whether the issue being addressed has trans-national aspects that cannot be properly regulated by action of Member States and/or their local and regional authorities;
ii) whether action by Member States alone would conflict with the requirements of the Treaty or would otherwise significantly damage the Member States' interests;
iii) whether existing Community measures or targeted assistance provided hereunder would be sufficient to achieve the intended objectives.

Article 152(5) of the Treaty generally sets out that "Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services" and, more specifically, that Community measures adopted in this area cannot result in any harmonisation of the laws and regulations of the Member States (Article 152(3)(c)). The proposal for a directive in question does not in any way infringe on the Member States' ability to define social and healthcare services or to organise and provide healthcare and social security benefits (see Recital 8). More specifically, it does not affect the extent of a patient's entitlement to reimbursement for healthcare provided by a Member State other than his/her State of habitual residence, stating that it "does not aim [...] 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" (Recital 25).

With regard to Article 5 of the Treaty, the measure under consideration seems necessary for the accomplishment of one of the Treaty's objectives, namely the completion of the internal market with respect to the freedom to provide services and, more specifically, healthcare services. Firstly, the directive sets out to codify, in line with the general principle of legal certainty and therefore entirely in the patient's interest, the most recent case law of the Court of Justice of the European Communities on the freedom to provide healthcare services (the most recent include ECJ Judgement, 16 May 2006, Case C-372/04, *Watts*; ECJ Judgement, 23 October 2003, Case C-56/01, *Inizan*). Secondly, it completes, by consolidating, existing EU regulatory instruments, including, mainly, the so-called Regulations for coordination of social security schemes, which the directive does not affect and which therefore remain in place. Indeed, it expressly endorses their prevalence (Article 3). Finally, the directive aims to achieve, as recalled, a uniform minimum level of protection for the right of access to healthcare and the right to benefit from medical treatment (in compliance with the relevant provisions

of the Charter of Fundamental Rights of the European Union), thereby allowing each State the right to maintain higher standards of protection.

3. Principle of proportionality

a) Do the proposed measures go beyond what is necessary to satisfactorily achieve the intended objectives? Please provide a reasoned answer while giving consideration to the following elements:

   i) whether the proposed form of action is as straightforward as possible (for example directives should be preferred to regulations and framework directives to detailed measures);
   ii) whether the proposed action leaves as much room for national decision as possible;
   iii) whether the proposed measures take account of well established national arrangements and special circumstances applying in your Member State or region (e.g. the organisation and functioning of the legal system).

It should be noted that, with regard the principle of proportionality, the proposal under consideration does not go beyond what is required to achieve its objectives. Firstly, with respect to the general consideration regarding the choice of regulatory instrument: as noted, directives are usually preferable to acts that leave narrower margins for Member State competences, such as regulations. More specifically, it should be pointed out that the basic principle underlying the proposed legislation, i.e. the obligation of the State of affiliation to reimburse an insured person who receives hospital care in another State, where such/equivalent care would have been covered by the compulsory social security system of the Member State of affiliation, is qualified by Article 8(3) and the system of prior authorisation it sets out. This raises the question as to whether the legal certainty requirement can actually be met in the light of such a provision, given that some of the parameters it refers to (and which, moreover, are those mentioned in the relevant Community case-law) remain fairly ambiguous. Also, with respect to the principle of proportionality, Article 11 of the proposal endorses the principle whereby in the case of cross-border treatment, the legislation of the Member State of treatment shall apply. Thus such a State is not subject to what would undoubtedly be a disproportionate obligation to apply the law of the patient's State of affiliation. The directive is clearly restricted to facilitating cooperation between Member States in the area of healthcare and does not appear to restrict Member State competences unduly in relation to its intended objectives.

b) If you consider that the proposed measures indeed go further than what is necessary, what would you consider to be a less restrictive, alternative way to achieve the intended objectives?

Refer to answer 3.1 above.

4. Financial and administrative burdens

a) Please indicate whether the financial and/or administrative burden falling upon the European Community, national governments, regional and local authorities, economic operators and

citizens is commensurate to the objectives of the proposal and whether it has been kept to an absolute minimum.

A comprehensive consideration of the financial and/or administrative impact of the proposal could, however, raise some doubts. Indeed, due to the concept and organisation of the Italian healthcare system, it is clear that the predominant impact of the proposal will in fact be felt by the regions. Needless the say, it is not a matter of defining the precise standard of healthcare entitlement (and the guarantees underlying its provision) since the definition of essential minimum standards for the provision of social care across the country is an exclusive Member State competence. It is firstly a matter of the unpredictable increase in costs that implementing such a measure could incur for the regions. Although it is true that in the Communication accompanying the proposal for a directive (COM(2008) 415 final, 2 July 2008), the Commission, on the one hand, estimates that around 1% of public healthcare budgets is spent on cross-border healthcare, (a figure it qualifies as "relatively small scale") and, on the other hand, that "the additional costs of treatment" arising from the implementation of the directive "would be a small fraction of one percent of overall health expenditures, and far outweighed by the benefits", these assessments, which are based on general mass-scale considerations, do not appear to take appropriate account of the (sometimes also consistent) differences between the regions of various Member States, not to mention of the same Member State, relating to the quantitative levels of healthcare already being provided today. Secondly, it can be seen that there is considerable difficulty in obtaining precise data at the regional and local levels concerning the other aspect of the situation, i.e. the efficient management of the so called outflow of patients. Recalling the abovementioned regional differences (even within the same State), it seems clear that even in this respect the regional and local impacts of the measure under consideration may not have been taken into proper account (it will be necessary to ensure that the outflow of patients is regulated in such a way as to avoid compromising the financial stability of the Member States' social security systems, or the planning and rationalisation of the hospital system).

Finally, the impact of innovations in non-hospital care is not easy to foresee, be it mobile treatment (remote prescription and treatment, telemedicine services …) or pharmaceutical services (remote prescription, pharmacy prescriptions in other countries, Community prescriptions…).

b) If the relevant data is available to you, please provide an estimation of the financial and/or administrative burden the implementation of the present proposal would entail for your administration and/or in the territory of your local or regional authority.

Refer to answer 4.1 above.

5. Consideration of local and regional factors in the impact assessment and consultation:

a) Has a comprehensive impact assessment been presented, which takes into account local and regional aspects?

There are grounds for questioning whether this proposal for a directive takes adequate account of regional and local specificities and needs.

Generally speaking, given the intended objectives of the directive, it seems difficult to imagine how it could be implemented successfully without the direct involvement of the regions. On the same note, therefore, it seems to follow that its implementation has to be coordinated by the various regions of the Member States which, under their respective national systems, have responsibility for public health. Furthermore, the proposal establishes a general duty of cooperation for Member States, and immediately envisages the possibility of establishing contact points at regional or local levels, stating that "[t]his is particularly the case for cooperation in border regions" (although in fact it seems clear that non-border regions will also be involved), which would for instance concern the joint planning, mutual recognition or adaptation of procedures or standards. It also suggests using the EGTC cooperation instrument (see Recitals 36-38). The recommendations forcefully put forward by the Committee of the Regions in its opinion on the Commission White Paper entitled "Together for Health: A Strategic Approach for the EU 2008-2013" (OJ C 172, 5 July 2008) are particularly resonant in this context. Having recalled that the local and regional authorities are directly affected by the new EU strategy, the Committee of the Regions emphasised that these authorities "are often responsible for the planning, management, operation and development of the health sector — and also frequently bear financial responsibility for this area too" and therefore calls for them to be fully involved in implementing the strategy and, before that, in policymaking itself (points 12-14). In operative terms, we could therefore suggest that where implementing the directive requires the practical involvement of the regional authorities under one of the abovementioned instruments, regional interests and needs have to be taken into due account even during the stages following the initial implementation of the directive, possibly through the direct involvement of the Committee of the Regions in the committees that will assist the Commission in the adoption of subsequent and necessary implementing provisions (Article 19).

b) Have local and regional authorities been adequately consulted prior to the adoption of the proposal? In case you have participated in such a consultation, please specify the practical details of your participation and provide an assessment of your experience.

Refer to answer 5.1 above.

6. Quality of the arguments provided:

a) Does the proposal provide clear, adequate and convincing arguments to justify its compliance with the subsidiarity and proportionality principles?

Refer to answer 4.1 above.

b) Are these arguments based on qualitative as well as quantitative indicators?

Refer to answer 4.1 above.

Further comments

Please feel free to provide additional feedback on the overall quality of the proposal, i.e. clarity of drafting, simplicity of implementation at the regional and local level, need for a more thorough debate within the course of the legislative process on the financial and/or administrative burden the proposal would entail, suitability of the envisaged action with regard to the intended objectives etc.

One point that the proposal for a directive does not address but which could - if broached - be of particular interest to the regions is the establishment of appropriate compensation/insurance formalities and arrangements for cases where a patient's country of affiliation is unable to reimburse the cost of treatment provided by another Member State. A "temporary protection" measure could, for instance, be set up as an ad hoc buffer fund, which would at least ensure that service providers were paid in case of non-payment by patients (and) weaker countries. In this case, it would also be necessary to make arrangements for setting up this fund which would not result in distortions and, consequently, higher costs for precisely those health systems which, being more attractive, are more exposed to the risk of non-payment for treatment provided.

17 October 2008

Name of the Authority:	Landeshauptleutekonferenz
Primary contact person:	Liaison office of the Federal Laender
Title of document:	Directive on the application of patients' rights in cross-border healthcare
Reference: **(e.g. COM(2005) 112)**	COM(2008) 414.

1. Legal basis and type of competence: a) Objective(s) of the document.	The main objective of the proposed directive is to enable access to (hospital and non-hospital) health services in other Member States and to facilitate cross-border provision of such services. In order for this to happen, it is envisaged that Member States will put the following conditions in place: patients using health services in another Member State are to be reimbursed, up to the amount which would have applied to the same or similar health service in the Member State of affiliation; requirements for prior authorisation of non-hospital treatment in another Member State are to be scrapped; restrictions are to apply to continued prior authorisation of hospital treatment in other Member States; patients are to have enforceable access to information on and provision of healthcare in other Member States. Impact on Austria: In Austria the costs of hospital care services are partly covered by social security funding and partly by fiscal funding used to make up the shortfall in hospital operating expenses. The proposal for a directive does not make it clear whether patients with insurance from another country can be charged a sufficient amount to cover costs or merely the share of costs which would have been covered by social security institutions in the their country of origin. In the latter case, a patient with insurance from another country could only be charged part of the costs for treatment in Austrian public sector hospitals, which depending on the number of patients with insurance from other countries using Austrian

15 If the competence is exclusive, the subsidiarity principle does not apply. If this is the case, please go directly to the proportionality section of this questionnaire.

	hospital services could significantly affect the financial balance of the Austrian healthcare system. Insofar as patients insured in one Member State decide to use hospital services in another Member State, the proposed directive provides for limited prior authorisation options. However, the wording of Article 8(3)(a) does not make it clear whether such a prior authorisation system could be at all feasible in Austria given the mixed basis for financing described here. Quite apart from this, in view of ECJ case law, which requires very strict interpretation of conditions for limitations on Community rights, it is doubtful whether the conditions for prior authorisation set out in Article 8(3)(a) and (b) would ever be applied. It is certain that in the absence of a prior authorisation procedure, social security institutions would face substantial additional costs, as social security contributes lump sums to hospital financing. This lump sum is set in an agreement between the federal government and the *Länder* on organising and financing healthcare. Consequently, each patient insured in their own country receiving hospital treatment in another Member State would mean additional expenditure for social security institutions. For non-hospital care, social security institutions in the country of affiliation would have to reimburse patients receiving health services in other Member States. Given that in Austria the majority of social security institutions (Regional Sickness Insurance Funds) provide lump sums for treatment by doctors with their own practices (panel and private doctors, i.e. doctors who accept all patients with health insurance and those who only accept certain categories), all treatment in other Member States will inevitably result in additional expenditure. It is therefore clear that the proposed directive is completely incorrect – at least for Austria – in assuming that there will be savings on the costs of hospital and non-hospital care at home when patients freely choose to use particular healthcare services abroad. Money will only be saved if there are genuine cuts in capacity (staff, buildings) or if the current system for financing hospital and non-hospital treatment on the basis of lump sum payments is

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	changed. However, cost savings on the basis of reduced capacity are only possible in the long-term and will require careful attention over many years, or probably even decades.
b) On which Treaty article(s) is the document based? If you consider the legal basis inappropriate, please give reasons.	The proposed directive is based on Article 95 TEC. It is doubtful whether the choice of Art. 95 TEC was a correct one. The main objective of the directive as set out in Chapter III, Articles 6-12 is to create a framework for access to healthcare in another Member State. It is true that Article 95 TEC is to be used to achieve the Internal Market objectives of Article 14 TEC. However, Article 95 TEC does not apply if the harmonisation of legislation in view of the Internal Market is covered by special legislation. Also, the main objective which the directive sets out to achieve has to do with the freedom to provide services, as regulated by Article 49 TEC. Further legislation on the liberalisation of particular services should be based on Article 52 in combination with Article 49 TEC. Given the above-mentioned effects, it is also doubtful whether the proposed directive is compatible with Article 152 TEC. As a cross-cutting clause, Article 152(1) TEC stipulates that a high level of health protection shall be ensured in the definition and implementation of all Community policies. Also, according to Article 152(5) TEC 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. The above discussion of the possible impact of the proposed directive in Austria shows that the proposed directive would endanger the undoubtedly high standard of Austrian healthcare, unless the system was reorganised. This effect would contradict the objectives of the TEC and is therefore incompatible with Community law.
c) Does the proposed action fall within the European Community's competences? Is such competence exclusive or shared between the Community and the Member States[15]?	Whether it is based on Article 95 or on Article 52 in combination with Article 49, this measure falls within an area of shared competence between the EU and Member States.

2. Subsidiarity principle Should action be taken at European level, because: a) such action is necessary insofar as the Member States (either at the central or at regional and local levels) cannot sufficiently achieve the objective of the proposed measure, and b) such action would have a clear benefit by reason of its scale or effects? Please provide a reasoned answer to the above question while giving consideration to the following: i) whether the issue being addressed has trans-national aspects that cannot be properly regulated by action of Member States and/ or their local and regional authorities; ii) whether action by Member States alone would conflict with the requirements of the Treaty or would otherwise significantly damage the Member States' interests; iii) whether existing Community measures or targeted assistance provided hereunder would be sufficient to achieve the intended objectives.	The main objective of the proposed directive – i.e. patient mobility in order to access cross-border healthcare services – is of a cross-border nature and requires action at EU level. However, such legislation already exists at EU level, with Art. 22 of Regulation 1408/71 and Art. 49 TEC, as well as the relevant ECJ judgments. Art. 22 of Regulation No. 1408/71 regulates cost-sharing between the relevant Member States in the event of emergency medical treatment or a patient needing to go abroad in order to receive appropriate treatment. Regulation No. 1408/71 lays down the basis for the provision of specialist services at the rates applied by the country providing the service. The ECJ has established a second system for patient mobility with various judgments on cross-border use of healthcare services (see e.g. Case C-120/95 Decker, Case C-158/96, Kohll, Case. C-368/98 Vanbraekel, and Case C-157/99 Graets-Smits and Peerbooms). Art. 49 TEC is of relevance to reimbursement of medical treatment at the rates applied in the country of affiliation. In addition, for healthcare services provided within a hospital, a prior authorisation system is compatible with Art. 49 TEC. The two systems are complementary, clear in terms of content, and do not require any further legislative development at EU level. Finally, it should be pointed out that the failure by certain individual Member States to transpose existing legislation into national law - particularly case law on Art. 49 TEC – does not warrant the proposed directive, given that Community law provides for other, more appropriate instruments which are only applicable to Member States in breach of their obligations.

3. Proportionality principle a) Do the proposed measures go beyond what is necessary to satisfactorily achieve the intended objectives?	Admittedly, the proposed directive is in theory appropriate as a means of enhancing patient mobility. However, it is disproportionate, given that a functioning

.../...

Please provide a reasoned answer while giving consideration to the following elements: i) whether the proposed form of action is as straightforward as possible (for example directives should be preferred to regulations and framework directives to detailed measures); ii) whether the proposed action leaves as much room for national decision as possible; iii) whether the proposed measures take account of well established national arrangements and special circumstances applying in your Member State or region (e.g. the organisation and functioning of the legal system).	system for patient mobility already exists at EU level – see Point 2. Further legislation is not needed. The proposed directive is particularly restrictive on prior authorisation of patient mobility in the field of hospital care, with insufficient scope for Member States to take the necessary decisions at national level.
b) If you consider that the proposed measures indeed go further than what is necessary, what would you consider to be a less restrictive, alternative way to achieve the intended objectives?	Information measures, which could be specified by European Commission guidelines, would suffice to make the existing rules on patient mobility and reimbursement sufficiently transparent for members of the public.

4. Financial and/or administrative burden: a) Please indicate whether the financial and/or administrative burden falling upon the European Community, national governments, regional and local authorities, economic operators and citizens is commensurate to the objectives of the proposal and whether it has been kept to an absolute minimum. b) If the relevant data is available to you, please provide an estimation of the financial and/or administrative burden the implementation of the present proposal would entail for your administration and/or in the territory of your local or regional authority.	The financial and administrative burden is disproportionate, especially in view of the fact that more modest measures would suffice (see Point 3); even though an alternative exists, the European Commission has opted for a directive involving additional implementation and running costs, among other things. In addition, the proposed directive denies there is any evidence "to suggest that such care (i.e. cross-border non-hospital healthcare) will undermine either the financial sustainability of health and social security systems overall or the organisation, planning and delivery of health services". However, this statement is unsubstantiated, especially given that the impact assessment lacks any detailed analysis of the implications for national healthcare systems, taking into account the differences between them.

Better Regulation and Preparation of the proposal	
5. Consideration of local and regional factors in the impact assessment and consultation: a) Has a comprehensive impact assessment been presented, which takes into account local and regional	An impact assessment has been carried out. However, this assessment cannot be considered as

.../...

aspects?	comprehensive, given that it lacks a convincing analysis of the implications for national healthcare systems, taking into account the differences between them. It also fails to take into account local and regional aspects.
b) Have local and regional authorities been adequately consulted prior to the adoption of the proposal? In case you have participated in such a consultation, please specify the practical details of your participation and provide an assessment of your experience.	A consultation was carried out, but without paying particular attention to local and regional authorities.
6. 6. Quality of the arguments provided: a) Does the proposal provide clear, adequate and convincing arguments to justify its compliance with the subsidiarity and proportionality principles? b) Are these arguments based on qualitative as well as quantitative indicators?	Both the proposed directive itself and the accompanying impact assessment briefly discuss the subsidiarity and proportionality principles. However, these discussions are lacking in substance and do not mention any figures.
Further comments Please feel free to provide additional feedback on the overall quality of the proposal, i.e. clarity of drafting, simplicity of implementation at the regional and local level, need for a more thorough debate within the course of the legislative process on the financial/ and or administrative burden the proposal would entail, suitability of the envisaged action with regard to the intended objectives etc.	

Name of the Authority:	Regional Parliament of Vorarlberg
Primary contact person:	
Title of document:	Directive on the application of patients' rights in cross-border healthcare
Reference: **(e.g. COM(2005) 112)**	COM(2008) 414.

1. Legal basis and type of competence: a) Objective(s) of the document.	The main objective of the proposed directive is to enable access to (hospital and non-hospital) health services in other Member States and to facilitate cross-border provision of such services. In order for this to happen, it is envisaged that Member States will put the following conditions in place: patients using health services in another Member State are to be reimbursed, up to the amount which would have applied to the same or similar health service in the Member State of affiliation; requirements for prior authorisation of non-hospital treatment in another Member State are to be scrapped; restrictions are to apply to continued prior authorisation of hospital treatment in other Member States; patients are to have enforceable access to information on and provision of healthcare in other Member States. Impact on Austria: In Austria the costs of hospital care services are partly covered by social security funding and partly by fiscal funding used to make up the shortfall in hospital operating expenses. The proposal for a directive does not make it clear whether patients with insurance from another country can be charged a sufficient amount to cover costs or merely the share of costs which would have been covered by social security institutions in the their country of origin. In the latter case, a patient with insurance from another country could only be charged part of the costs for treatment in Austrian public sector hospitals, which depending on the number of patients with insurance from other countries using Austrian

16 If the competence is exclusive, the subsidiarity principle does not apply. If this is the case, please go directly to the proportionality section of this questionnaire.

	hospital services could significantly affect the financial balance of the Austrian healthcare system. Insofar as patients insured in one Member State decide to use hospital services in another Member State, the proposed directive provides for limited prior authorisation options. However, the wording of Article 8(3)(a) does not make it clear whether such a prior authorisation system could be at all feasible in Austria given the mixed basis for financing described here. Quite apart from this, in view of ECJ case law, which requires very strict interpretation of conditions for limitations on Community rights, it is doubtful whether the conditions for prior authorisation set out in Article 8(3)(a) and (b) would ever be applied. It is certain that in the absence of a prior authorisation procedure, social security institutions would face substantial additional costs, as social security contributes lump sums to hospital financing. This lump sum is set in an agreement between the federal government and the *Länder* on organising and financing healthcare. Consequently, each patient insured in their own country receiving hospital treatment in another Member State would mean additional expenditure for social security institutions. For non-hospital care, social security institutions in the country of affiliation would have to reimburse patients receiving health services in other Member States. Given that in Austria the majority of social security institutions (Regional Sickness Insurance Funds) provide lump sums for treatment by doctors with their own practices (panel and private doctors, i.e. doctors who accept all patients with health insurance and those who only accept certain categories), all treatment in other Member States will inevitably result in additional expenditure. It is therefore clear that the proposed directive is completely incorrect – at least for Austria – in assuming that there will be savings on the costs of hospital and non-hospital care at home when patients freely choose to use particular healthcare services abroad. Money will only be saved if there are genuine cuts in capacity (staff, buildings) or if the current system for financing hospital and non-hospital treatment on the basis of lump sum payments is

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	changed. However, cost savings on the basis of reduced capacity are only possible in the long-term and will require careful attention over many years, or probably even decades.
b) On which Treaty article(s) is the document based? If you consider the legal basis inappropriate, please give reasons.	The proposed directive is based on Article 95 TEC. It is doubtful whether the choice of Art. 95 TEC was a correct one. The main objective of the directive as set out in Chapter III, Articles 6-12 is to create a framework for access to healthcare in another Member State. It is true that Article 95 TEC is to be used to achieve the Internal Market objectives of Article 14 TEC. However, Article 95 TEC does not apply if the harmonisation of legislation in view of the Internal Market is covered by special legislation. Also, the main objective which the directive sets out to achieve has to do with the freedom to provide services, as regulated by Article 49 TEC. Further legislation on the liberalisation of particular services should be based on Article 52 in combination with Article 49 TEC. Given the above-mentioned effects, it is also doubtful whether the proposed directive is compatible with Article 152 TEC. As a cross-cutting clause, Article 152(1) TEC stipulates that a high level of health protection shall be ensured in the definition and implementation of all Community policies. Also, according to Article 152(5) TEC 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. The above discussion of the possible impact of the proposed directive in Austria shows that the proposed directive would endanger the undoubtedly high standard of Austrian healthcare, unless the system was reorganised. This effect would contradict the objectives of the TEC and is therefore incompatible with Community law.
c) Does the proposed action fall within the European Community's competences? Is such competence exclusive or shared between the Community and the Member States[16]?	Whether it is based on Article 95 or on Article 52 in combination with Article 49, this measure falls within an area of shared competence between the EU and Member States.

2. Subsidiarity principle Should action be taken at European level, because: a) such action is necessary insofar as the Member States (either at the central or at regional and local levels) cannot sufficiently achieve the objective of the proposed measure, and b) such action would have a clear benefit by reason of its scale or effects? Please provide a reasoned answer to the above question while giving consideration to the following: i) whether the issue being addressed has trans-national aspects that cannot be properly regulated by action of Member States and/ or their local and regional authorities; ii) whether action by Member States alone would conflict with the requirements of the Treaty or would otherwise significantly damage the Member States' interests; iii) whether existing Community measures or targeted assistance provided hereunder would be sufficient to achieve the intended objectives.	The main objective of the proposed directive – i.e. patient mobility in order to access cross-border healthcare services – is of a cross-border nature and requires action at EU level. However, such legislation already exists at EU level, with Art. 22 of Regulation 1408/71 and Art. 49 TEC, as well as the relevant ECJ judgments. Art. 22 of Regulation No. 1408/71 regulates cost-sharing between the relevant Member States in the event of emergency medical treatment or a patient needing to go abroad in order to receive appropriate treatment. Regulation No. 1408/71 lays down the basis for the provision of specialist services at the rates applied by the country providing the service. The ECJ has established a second system for patient mobility with various judgments on cross-border use of healthcare services (see e.g. Case C-120/95 Decker, Case C-158/96, Kohll, Case. C-368/98 Vanbraekel, and Case C-157/99 Graets-Smits and Peerbooms). Art. 49 TEC is of relevance to reimbursement of medical treatment at the rates applied in the country of affiliation. In addition, for healthcare services provided within a hospital, a prior authorisation system is compatible with Art. 49 TEC. The two systems are complementary, clear in terms of content, and do not require any further legislative development at EU level. Finally, it should be pointed out that the failure by certain individual Member States to transpose existing legislation into national law - particularly case law on Art. 49 TEC – does not warrant the proposed directive, given that Community law provides for other, more appropriate instruments which are only applicable to Member States in breach of their obligations.

3. Proportionality principle a) Do the proposed measures go beyond what is necessary to satisfactorily achieve the intended objectives?	Admittedly, the proposed directive is in theory appropriate as a means of enhancing patient mobility. However, it is disproportionate, given that a functioning

.../...

Please provide a reasoned answer while giving consideration to the following elements: i) whether the proposed form of action is as straightforward as possible (for example directives should be preferred to regulations and framework directives to detailed measures); ii) whether the proposed action leaves as much room for national decision as possible; iii) whether the proposed measures take account of well established national arrangements and special circumstances applying in your Member State or region (e.g. the organisation and functioning of the legal system).	system for patient mobility already exists at EU level – see Point 2. Further legislation is not needed. The proposed directive is particularly restrictive on prior authorisation of patient mobility in the field of hospital care, with insufficient scope for Member States to take the necessary decisions at national level.
b) If you consider that the proposed measures indeed go further than what is necessary, what would you consider to be a less restrictive, alternative way to achieve the intended objectives?	Information measures, which could be specified by European Commission guidelines, would suffice to make the existing rules on patient mobility and reimbursement sufficiently transparent for members of the public.

4. Financial and/or administrative burden: a) Please indicate whether the financial and/or administrative burden falling upon the European Community, national governments, regional and local authorities, economic operators and citizens is commensurate to the objectives of the proposal and whether it has been kept to an absolute minimum. b) If the relevant data is available to you, please provide an estimation of the financial and/or administrative burden the implementation of the present proposal would entail for your administration and/or in the territory of your local or regional authority.	The financial and administrative burden is disproportionate, especially in view of the fact that more modest measures would suffice (see Point 3); even though an alternative exists, the European Commission has opted for a directive involving additional implementation and running costs, among other things. In addition, the proposed directive denies there is any evidence "to suggest that such care (i.e. cross-border non-hospital healthcare) will undermine either the financial sustainability of health and social security systems overall or the organisation, planning and delivery of health services". However, this statement is unsubstantiated, especially given that the impact assessment lacks any detailed analysis of the implications for national healthcare systems, taking into account the differences between them.

Better Regulation and Preparation of the proposal	
5. Consideration of local and regional factors in the impact assessment and consultation: a) Has a comprehensive impact assessment been presented, which takes into account local and regional	An impact assessment has been carried out. However, this assessment cannot be considered as

.../...

aspects?	comprehensive, given that it lacks a convincing analysis of the implications for national healthcare systems, taking into account the differences between them. It also fails to take into account local and regional aspects.
b) Have local and regional authorities been adequately consulted prior to the adoption of the proposal? In case you have participated in such a consultation, please specify the practical details of your participation and provide an assessment of your experience.	A consultation was carried out, but without paying particular attention to local and regional authorities.
6. 6. Quality of the arguments provided: a) Does the proposal provide clear, adequate and convincing arguments to justify its compliance with the subsidiarity and proportionality principles? b) Are these arguments based on qualitative as well as quantitative indicators?	Both the proposed directive itself and the accompanying impact assessment briefly discuss the subsidiarity and proportionality principles. However, these discussions are lacking in substance and do not mention any figures.
Further comments Please feel free to provide additional feedback on the overall quality of the proposal, i.e. clarity of drafting, simplicity of implementation at the regional and local level, need for a more thorough debate within the course of the legislative process on the financial/ and or administrative burden the proposal would entail, suitability of the envisaged action with regard to the intended objectives etc.	

Name of the Authority:	The City of Lodz Office
Primary contact person:	
Title of document:	Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare
Reference: **(e.g. COM(2005)112)**	COM(2008) 414 – final version

1. Legal basis & type of competence:	
a) Objective(s) of the document.	a) The objective is to ensure that there is a clear framework for cross-border healthcare within the EU and ensuring compliance with common healthcare principles for cross-border healthcare what results from ensuring free flow of healthcare services.
b) On which Treaty article(s) is the document based? If you consider the legal basis inappropriate, please give reasons.	b) The proposal is based on Article 95 of Treaty of UE.
c) Does the proposed action fall within the European Community's competences? Is such competence exclusive or shared between the Community and the Member States[17]?	c) Competence divided between the Community and Member States.

2. Subsidiarity principle	
Should action be taken at European level, because (a) such action is necessary insofar as the Member States (either at the central or at regional and local levels) cannot sufficiently achieve the objective of the proposed measure, and (b) such action would have a clear benefit by reason of its scale or effects? Please provide a reasoned answer to the above question while giving consideration to the following: i) whether the issue being addressed has trans-national aspects that cannot be properly regulated by action of Member	The subject of the regulation has many Community-wide trans-national aspects. Taking actions on the European level is essential, because Member States are not able to achieve proposed purposes on their own and provide greater clarity and certainty regarding Community law. Actions undertaken by Member States alone would pose a threat to the safe and efficient provision of cross-border healthcare. However, Community action will contribute to proper providing of this care and will facilitate European cooperation on healthcare.

[17] If the competence is exclusive, the subsidiarity principle does not apply. If this is the case, please go directly to the proportionality section of this questionnaire.

States and/ or their local and regional authorities; ii) whether action by Member States alone would conflict with the requirements of the Treaty or would otherwise significantly damage the Member States' interests; iii) whether existing Community measures or targeted assistance provided hereunder would be sufficient to achieve the intended objectives.	

3. Proportionality principle: a) Do the proposed measures go beyond what is necessary to satisfactorily achieve the intended objectives? Please provide a reasoned answer while giving consideration to the following elements: i) whether the proposed form of action is as straightforward as possible (for example directives should be preferred to regulations and framework directives to detailed measures). ii) whether the proposed action leaves as much room for national decision as possible. iii) whether the proposed measures take account of well established national arrangements and special circumstances applying in your Member State or region (e.g. the organisation and functioning of the legal system). b) If you consider that the proposed measures indeed go further than what is necessary, what would you consider to be a less restrictive, alternative way to achieve the intended objectives?	The proposed measures are appropriate to intended purposes. Accepted form of the solution – directive – is binding the Member States only for purposes, which should be achieved, leaving to them the freedom of choice of the form and resources of their realisation. This directive is ensuring the respect of the responsibilities of the Member States for the health systems with the organisation and delivery of health systems in it. It is important to underline that this do not alter the Member States' choice of the rules which will be applicable to a specific case. The impact of the cross-border healthcare under this directive does not undermine health and social security systems – either through its financial impact or through its impact on planning and management of those systems.

4. Financial and/or administrative burden: a) Please indicate whether the financial and/or administrative burden falling upon the European Community, national governments, regional and local authorities, economic operators and citizens is commensurate to the objectives of the proposal and whether it has been kept to an absolute minimum.	a) Predicted responsibilities, necessary for the realisation of the directive' purposes, are appearing appropriate for this purposes.

.../...

b) If the relevant data is available to you, please provide an estimation of the financial and/ or administrative burden the implementation of the present proposal would entail for your administration and/ or in the territory of your local or regional authority.	b) Estimation of expenses necessary to put the directive into practice is not possible at the present stage.

Better Regulation & Preparation of the proposal	
5. Consideration of local and regional factors in the impact assessment and consultation a) Has a comprehensive impact assessment been presented, which takes into account local and regional aspects?	a) Yes
b) Have local and regional authorities been adequately consulted prior to the adoption of the proposal? In case you have participated in such a consultation, please specify the practical details of your participation and provide an assessment of your experience.	b) Yes. The proposal was reviewed by the Department of the Public Health of the City of Lodz Office.
6. Quality of the arguments provided: a) Does the proposal provide clear, adequate and convincing arguments to justify its compliance with the subsidiarity and proportionality principles?	a) Yes.
b) Are these arguments based on qualitative as well as quantitative indicators?	b) Presented arguments have mainly substantial character, being based also on opinion polls and surveys, which they pointed that the meaning percent of the citizens in the European Union are not aware of the possibility to receive healthcare outside their country of health insurance, whereas patients and workers of the health care often have difficulties with establishing entitlements to the reimbursement of costs of the cross-border health care.
Further comments Please feel free to provide additional feedback on the overall quality of the proposal, i.e. clarity of drafting, simplicity of implementation at the regional and local level, need for a more thorough debate within the course of the legislative process on the financial/ and or administrative burden the proposal would entail, suitability of the envisaged action with regard to the	

.../...

intended objectives etc.	

Regional Government of the Azores

1. Legal basis TYPE of competence:

1.1 Objective(s) of the document.

The document aims to present the purpose of the proposal for directive that intents to provide EU citizens healthcare in another Member State, when their country of residence cannot provide a specific treatment, thus allowing a true free movement of health services

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1.2 On which Treaty article(s) is the document based? If you consider the legal basis inappropriate, please give reasons.

This document is based on articles 95 and 152 of the Treaty

1.3 Does the proposed action fall within the European Community's competences? Is such competence exclusive or shared between the Community and the Member States ?

The proposed action falls within the Community's competences, and such competence is shared with the Member States, since the organisation of each Member State's health and social security systems has to be taken into account in order to enable the application of this directive.

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2. Subsidiarity principle

2.1 Should action be taken at European level, because
(a) such action is necessary insofar as the Member States (either at the central or at regional and local levels) cannot sufficiently achieve the objective of the proposed measure, and
(b) such action would have a clear benefit by reason of its scale or effects?
Please provide a reasoned answer to the above question while giving consideration to the following:
i) whether the issue being addressed has trans-national aspects that cannot be properly regulated by action of Member States and/ or their local and regional authorities;
ii) whether action by Member States alone would conflict with the requirements of the Treaty or would otherwise significantly damage the Member States' interests;
iii) whether existing Community measures or targeted assistance provided hereunder would be sufficient to achieve the intended objectives.

The action should be taken at the European level, because the Member States or the regional or local authorities cannot sufficiently attain the proposed objective alone. a) Such action as clear benefits by reason of its scale, since we are dealing with trans-national aspects that cannot be properly regulated by the action of a Member State or of its regional or local authorities. Moreover, the action of a single Member State would significantly damage the interests of the EU, as a whole, and consequently of the Member States. Existing Community measures or targeted assistance would not be sufficient to attain the goal of the document under analysis, since this issue requires an innovative and concerted action from the Community, because there are no certainties about its future development.

.../...

3. Proportionality principle:

3.1 Do the proposed measures go beyond what is necessary to satisfactorily achieve the intended objectives? Please provide a reasoned answer while giving consideration to the following elements:

i) whether the proposed form of action is as straightforward as possible (for example directives should be preferred to regulations and framework directives to detailed measures).

ii) whether the proposed action leaves as much room for national decision as possible.

iii) whether the proposed measures take account of well established national arrangements and special circumstances applying in your Member State or region (e.g. the organisation and functioning of the legal system).

The proposed measures do not go beyond what is necessary, since they take into account the different health and social security systems of each Member State, leaving some room for decision for the Members States and even for their regional and local authorities, with the proposals' action taking the form of a directive.

3.2 If you consider that the proposed measures indeed go further than what is necessary, what would you consider to be a less restrictive, alternative way to achieve the intended objectives?

Please check the answer above

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4. Financial and/or administrative burden:

4.1 Please indicate whether the financial and/or administrative burden falling upon the European Community, national governments, regional and local authorities, economic operators and citizens is commensurate to the objectives of the proposal and whether it has been kept to an absolute minimum.

a) We do not consider that the financial and administrative burden for the Member States and particularly for citizens was kept to a minimum, since the application of this proposal for directive will depend on the social security systems of the different Member States, that is to say, depend on the capacity or on the lack of it to reimburse the costs associated with treatments received in another Member State. In addition, it is clear in the document under analysis that citizens have to take the risk of additional costs.

4.2 If the relevant data is available to you, please provide an estimation of the financial and/ or administrative burden the implementation of the present proposal would entail for your administration and/ or in the territory of your local or regional authority.

b) We do not consider that the available data permits an estimation of the costs for the application of such a proposal in what regards the Azorean regional government; nonetheless, one has to take into account that we are an outermost region, and it is necessary to add the costs associated with the distance from the main European centres.

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5. Consideration of local and regional factors in the impact assessment and consultation

5.1 Has a comprehensive impact assessment been presented, which takes into account local and

.../...

regional aspects?

a) We consider that local and regional aspects were taken into account but in a minimal way. Nevertheless, we reckon that the comprehensive impact assessment was presented.

5.2 Have local and regional authorities been adequately consulted prior to the adoption of the proposal? In case you have participated in such a consultation, please specify the practical details of your participation and provide an assessment of your experience.

b) We do not consider that local and regional authorities have been adequately consulted for the adoption of this proposal for directive. Nonetheless, we think that it would have been important to consult the regional authorities, due to the sensibility of the issue in hand.

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6. Quality of the arguments provided:

6.1 Does the proposal provide clear, adequate and convincing arguments to justify its compliance with the subsidiarity and proportionality principles?

a) The proposal provides clear and convincing arguments to justify its compliance with the subsidiarity and proportionality principles, since it is perfectly clear that the initiative should be taken by the Community, as a whole, and not by the Member States individually.

6.2 Are these arguments based on qualitative as well as quantitative indicators?

b) Yes, these arguments are based on qualitative as well as quantitative indicators.

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7. Further comments

7.1 Please feel free to provide additional feedback on the overall quality of the proposal, i.e. clarity of drafting, simplicity of implementation at the regional and local level, need for a more thorough debate within the course of the legislative process on the financial/ and or administrative burden the proposal would entail, suitability of the envisaged action with regard to the intended objectives etc.

We consider that further debate should take place, specifically involving the regional authorities which have their own health system. Additional explanation should also be provided to make clearer the way in which the reimburse of treatments received in a Member State other than the one of residence will be done; although, it is our understating that the proposal leaves room for decision for the Members States. Nonetheless, the fact that citizens have to assume the risk of additional costs is a matter of concern.

Finnish Local and Regional Authorities

1. Legal basis TYPE of competence:

1.1 Objective(s) of the document.

The aim of the proposal is to clarify the patients' rights in the situations when they seek treatment in another Member State. There are also goals for cooperation between the Member States in cross-border healthcare.

1.2 On which Treaty article(s) is the document based? If you consider the legal basis inappropriate, please give reasons.

Treaty art 95.

1.3 Does the proposed action fall within the European Community's competences? Is such competence exclusive or shared between the Community and the Member States ?

The proposed action fall within the competences of the EC.

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2. Subsidiarity principle

2.1 Should action be taken at European level, because
(a) such action is necessary insofar as the Member States (either at the central or at regional and local levels) cannot sufficiently achieve the objective of the proposed measure, and
(b) such action would have a clear benefit by reason of its scale or effects?
Please provide a reasoned answer to the above question while giving consideration to the following:
i) whether the issue being addressed has trans-national aspects that cannot be properly regulated by action of Member States and/ or their local and regional authorities;
ii) whether action by Member States alone would conflict with the requirements of the Treaty or would otherwise significantly damage the Member States' interests;
iii) whether existing Community measures or targeted assistance provided hereunder would be sufficient to achieve the intended objectives.

It is necessary that in this area action is taken at European level. This issue has significant trans-national and cross-border aspects and thus Member States could not regulate it at national level only. The existing Community measures (e.g. Regulation on the coordination of Social Security 1408/71, the jurisdiction of the Court) are not sufficient to achieve clarity and anticipation.

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3. Proportionality principle:

3.1 Do the proposed measures go beyond what is necessary to satisfactorily achieve the intended objectives? Please provide a reasoned answer while giving consideration to the following elements:
i) whether the proposed form of action is as straightforward as possible (for example directives should be preferred to regulations and framework directives to detailed measures).
ii) whether the proposed action leaves as much room for national decision as possible.

.../...

iii) whether the proposed measures take account of well established national arrangements and special circumstances applying in your Member State or region (e.g. the organisation and functioning of the legal system).

In the proposed directive there are several articles that still need to be clarified. The impact of the directive on the different healthcare systems in Member States has to be studied more thoroughly. Without this kind of an analysis it is difficult to say if there are in the directive proposed measures that go beyond what is necessary to achieve the intended objectives.

3.2 If you consider that the proposed measures indeed go further than what is necessary, what would you consider to be a less restrictive, alternative way to achieve the intended objectives?

n/a

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4. Financial and/or administrative burden:

4.1 Please indicate whether the financial and/or administrative burden falling upon the European Community, national governments, regional and local authorities, economic operators and citizens is commensurate to the objectives of the proposal and whether it has been kept to an absolute minimum.

The financial and administrative duties of local and regional authorities may increase. There are still several uncertainties (e.g. reimbursement system public/private care, who is responsible to pay the costs: state or local authorities; health inequalities caused by the fact that patients pay first and get reimbursed later, travel expences). These uncertain ties make it difficult to determine wheather the financial burden is commensurate to the objectives of the directive.

4.2 If the relevant data is available to you, please provide an estimation of the financial and/ or administrative burden the implementation of the present proposal would entail for your administration and/ or in the territory of your local or regional authority.

It is not possible to present an estimation of the financial or administrative burden to be caused by the directive. Different social security systems (insurance based, tax financed or mix of both) make it difficult to foresee the prices of the healthcare costs: do you count the investment costs to the real costs of the treatment?

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5. Consideration of local and regional factors in the impact assessment and consultation

5.1 Has a comprehensive impact assessment been presented, which takes into account local and regional aspects?

Not to our knowledge.

5.2 Have local and regional authorities been adequately consulted prior to the adoption of the proposal? In case you have participated in such a consultation, please specify the practical

.../...

details of your participation and provide an assessment of your experience.

The Association of Finnish Local and Regional Authorities took part in the consultation organised by the European Commission. The Association was consulted by the Finnish Ministry of Social Affairs and Health in the coordination committee that is chaired by the Ministry. We also gave the written comments to the opinion of the Finnish Government.

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6. Quality of the arguments provided:

6.1 Does the proposal provide clear, adequate and convincing arguments to justify its compliance with the subsidiarity and proportionality principles?

The arguments to justify the proposal's compliance with the subsidiarity principle are clear. Estimating the compliance with the proportionality principle seems to need further analysis because of the questions that the provisions and uncertainties of the directive raise.

6.2 Are these arguments based on qualitative as well as quantitative indicators?

n/a

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7. Further comments

7.1 Please feel free to provide additional feedback on the overall quality of the proposal, i.e. clarity of drafting, simplicity of implementation at the regional and local level, need for a more thorough debate within the course of the legislative process on the financial/ and or administrative burden the proposal would entail, suitability of the envisaged action with regard to the intended objectives etc.

n/a
