Analysis drafted by the secretariat of the DEVE Commission and the subsidiarity unit

PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON THE APPLICATION OF PATIENTS' RIGHTS IN CROSS-BORDER HEALTHCARE
COM(2008) 414 FINAL

Rapporteur: Mr Karsten Uno Petersen (DK/PES)

1. The committee of the regions' key messages

The secretariat wishes to put forward a number of key messages that the CoR could convey to the Commission. In no way are these binding on the rapporteur:

- comply with the subsidiarity principle;
- do not undermine the 'financial balance' of national health systems;
- overcome difficulties in implementing the directive;
- boost cross-border healthcare cooperation in a manner that benefits cross-border regions.

2. Relevance to the Committee of the Regions

Local and regional authorities are directly concerned by this draft directive, since, in a number of Member States, they are responsible for health services and healthcare respectively.

3. Suggestions for the rapporteur

The secretariat wishes to put forward a number of points that the rapporteur could use when drawing up his/her draft opinion. In no case are these points binding on the rapporteur.

3.1 General comments

3.1.1 Comply with the subsidiarity principle

Healthcare is primarily the responsibility of the Member States. The role of the European Union, in light of the European treaties, is to adopt measures that complement the work of the Member States, for example in the field of cross-border health threats, patient mobility and reducing inequalities in health. What is needed, in practical, political and even symbolic terms, is to strike the right balance between the dynamics of European cooperation, the value of which is universally acknowledged, and compliance with the principle of subsidiarity, as embodied by the Member States, who remain the guarantors of the smooth operation of health systems. (See point 3.2 for a more detailed analysis of subsidiarity-related issues).

.../...

3.1.2 Do not undermine the 'financial balance' of national health systems

Since the Kohll/Decker judgments delivered by the European Court of Justice (see point 2.1), it has become clear that healthcare services can no longer be considered to operate in isolation in each EU Member State. The increasing flow of patients travelling from one Member State to another is sometimes the result of individual choice and sometimes the outcome of a decision taken by health ministers or sickness insurance schemes. There is a broad consensus among the Member States, however, that the movement of patients should not undermine the "financial balance" of national health systems within the European Union. The amounts at stake in the field of patient mobility are currently small (estimated to be around 1% of national health expenditure). It would be a mistake, however, to underestimate the potential impact of this phenomenon. Indeed, at the local level, the effects could be considerable and could even destabilise care providers in the regions concerned (in practice, these are the border regions, but also the smaller Member States).

3.1.3 Overcome the difficulties in implementing the directive

What is needed here is to set out a clear legal framework whilst guaranteeing a degree of discretion. This requirement for rigour is necessary first of all to facilitate cooperation, but also for obvious ethical reasons where patients are concerned. What is important is to ensure that they are properly cared for in both medical and administrative terms and are not forced to run medical, legal or financial risks. A number of barriers to the directive's implementation can be identified at this point:

- there is still uncertainty surrounding the issue of prior authorisation and the precise form of this prior authorisation needs to be established. The Court refers to the distinction between hospital care and outpatient care (which does not require prior authorisation). This classification was reasonably logical, because hospital care, in particular stays in hospital, were traditionally quite expensive. Recent developments in medical techniques, however, (in particular the continuing progress in outpatient surgery and, broadly speaking, more frequent consultation of general practitioners for conditions previously dealt with at hospital makes this classification somewhat obsolete. In addition to the distinction between hospital care and non-hospital care, it would probably be useful to consider the cost of certain techniques and draw up a European-level list of "particularly expensive techniques" that would justify prior authorisation, regardless of the concept of hospitalisation;
- the definition of hospital and non-hospital care, which varies from one country to another, could lead to problems concerning the need for prior authorisation. The proposal could result in an increase in different types of legal claims, unless the Member States set extremely clear rules for prior authorisation and conditions for reimbursement;
- on the basis of the results of one project funded at the European level (HealthBasket), which concludes that health services in the EU-27 cannot be compared (given the considerable differences in terms of care provided and care costs), some people claim that it would be impossible to set up a reimbursement scheme that proposes to reimburse identical or comparable healthcare received abroad in line with national scales for equivalent care, as stipulated in the Commission proposal. For such a scheme to work, a proposal should be made to establish

treatment packages to which everyone in Europe would be entitled and the prices of which would be agreed on. But does the European Union still have competence in this matter?

- there is also a risk that the directive will increase inequalities in healthcare, because patients will have to pay in advance for care received abroad and bear the financial risk of any further costs that might arise;
- lastly, the most vulnerable categories of patient must also be able to exercise the rights conferred on them by Community legislation. This will require clear information being available where people require it.

3.1.4 Boost cross-border healthcare cooperation in a manner that benefits cross-border regions.

The successive restructuring of national health systems as a result of the single market and competition policy in the European Union increases competition in the healthcare sector at the European level. The European Health Insurance card, greater patient mobility, the European directive on services and the opening-up of the healthcare market are other developments that illustrate this trend.

The existence of more porous borders in the healthcare sector not only increases competition between service providers but also creates all sorts of opportunities based on the following fundamental concept: if healthcare infrastructure and the corresponding resources are utilised at the cross-border level, they can be used to better effect. The increasing complexity of medical equipment and the growing specialisation of medicine mean precisely that a greater geographical area can be served. Cross-border cooperation in the healthcare sector thus enables the work of service providers to be more effectively dispersed, irrespective of political borders, which should lead to lower costs and, in the longer term, to an across-the-board improvement in the services provided. In light of the increased spending on healthcare and the greater specialisation in medicine, there appears to be a growing awareness in Europe's border regions of the urgent need to keep moving in this direction[1].

The success achieved in the field of cross-border hospital cooperation[2] should not disguise the serious obstacles encountered by project managers. In addition to physical obstacles (such as seas, mountains, sparsely-populated areas, etc.,) that make contact more difficult and more costly, stakeholders in cooperation come up against three main types of problem: cultural and linguistic barriers, administrative and regulatory problems (linked to the different levels of decision-making on the two sides of a border or to legal and regulatory barriers), and lastly, problems of operational and financial organisation.

The solutions to improving cross-border cooperation in healthcare furthermore involve not only raising awareness amongst stakeholders but also integrating cross-border healthcare into national and

1 Opinion of the Association of European Border Regions (AEBR) on cross-border health care of 10 March 2006.

2 The earliest projects in the field of cross-border health services date back to the 1970s, most significantly along the German-Dutch border and along the Upper Rhine. Today, almost all regions at the EU's internal and external borders are addressing this issue. The AEBR knows of almost 400 individual projects.

European planning measures as well as legal and administrative reforms and providing operational support to project managers. This draft directive represents a first step towards regulating cross-border cooperation at the European level.

3.2 Subsidiarity, proportionality and better lawmaking (analysis produced by the subsidiarity unit)

3.2.1 Legal Basis

- It has been long established in the case law of the European Court of Justice (ECJ) that healthcare is a "service" in the sense of article 50 of the EC Treaty (TEC). Thus measures geared towards the establishment of the internal market in cross-border healthcare are to be taken under article 95 of the EC Treaty. It should be however noted that measures enacted under this legal basis have to provided for a high level of protection for health (art. 95 par. 3 TEC), while such a high level of protection has to be at the same time ensured in the conception and implementation of all EC policies (art. 152 par. 1 TEC).
- Both free movement of services and public health are matters belonging to the shared competences of the Community. Therefore for the evaluation of legislative proposals in these sectors both the subsidiarity and proportionality principles are of relevance.
- It should be underlined that the EC Treaty mandates that action taken in the area of public health must fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care (art. 152 par. 5 TEC). This statement makes it clear that the Member States retain their sovereign powers in this field. However, the ECJ has specified that this does not exclude the possibility of Member States having to make adjustments to their national social security systems[3].

3.2.2 Compliance with the principle of subsidiarity

- Achieving the internal market in cross-border healthcare and establishing patients' rights for reimbursement of healthcare provided in other Member State in a clear-cut way is not a matter that can be left to be regulated only by the Member States or their local and regional authorities. By its very nature cross-border health care exhibits transnational elements (especially evident in border and remote regions) and the related challenges cannot be satisfactorily faced by the Member States.
- The Directive does not call in question the way the Member States (and if the case may be, their regional or local authorities) choose to organise their health system and medical care (art 152 par. 5 TEC). It does not change the right of Member States to determine the kind of benefits they choose to provide within their healthcare systems nor does it create an automatic entitlement for patients to have treatments abroad, where such treatments are not provided by the Member State of affiliation. However, the Commission does concede that the implementation of the Directive might imply that Member States would have to make adjustments to their national healthcare and

3 C-372/04 *Watts, European Court reports 2006 Page I-4325, par. 146-147.*

social security systems, but it does not consider that such an eventuality would undermine their sovereign powers in the field of healthcare.

- A question might arise as to how the Member States ensure their responsibility for treatment provided on their territories according to the principles of universality, access to good quality health care. Equity and solidarity. Article 5 of the proposed Directive mentions that Member States should define quality and safety standards for healthcare and enumerates elements that the definition of such standards must be accompanied by. It is not thought that the existence of such standards would put in question the powers of the Member States in the field of health, although the way in which these standards may be set (guidelines developed by the Commission with the collaboration of the Member States) could be open to criticism (see section on better regulation).

3.2.3 Compliance with the principle of proportionality

- It is supported that the present proposal for a Directive sets out only general principles, whilst leaving a wide margin for implementation to the Member States according to the their national, regional and local circumstances.
- It is also stated that the proposal respects the organisation of the Member States' health system and medical care (art 152 par. 5 TEC).
- Notwithstanding the above, it could be argued that the proposed Directive could in fact provide more detailed guidance to the Member States and their regional and local authorities on the circumstances under which they can be entitled to introduce a prior authorisation requirement for hospital care sought abroad. Taking into account that one of the aims of the proposal is to provide greater clarity to patients and Member States alike regarding the principles enounced in the jurisprudence of the ECJ regarding the application of patients' rights, article 8 par. 3 the Directive could be seen as quite vague. Although the conditions under which the prior authorisation system can be installed are mentioned, there is nothing said about the standard of proof that shall be met by Member States and their administrations in order to justify such a system. In fact the explanatory memorandum to the proposal states that the Member States have to provide evidence that the conditions justifying the establishment of the prior authorisation system are met, albeit no further clarification is provided.
- As far as the financial or administrative burdens flowing from the eventual implementation of the proposed Directive are concerned, the Commission supports that the impact of cross-border healthcare is not likely to give rise to major changes to the health system overall, given that the size of cross-border healthcare is expected to remain marginal. Putting however in motion the various requirements prescribed by the Directive (i.e. structures to provide information patients, setting up national contact points, measures to ensure the interoperability of e-health systems etc) will necessarily entail substantial costs for the authorities concerned, but these can be judged to be commensurate to the perceived benefits from the facilitation of cross-border healthcare.
- It can be observed that the impact assessment presented by the Commission only marginally addresses the possible territorial impacts of the proposed directive.

3.2.4 Better regulation

- As has been mentioned above in section B, the Commission proposes to issue guidelines (in cooperation with the Member States), which would specify the quality and safety standards of healthcare provided in the Member States. Such a proposal could be questionable in view of the fact that the adoption of guidelines in such a way would not involve the European Parliament, the Committee of the Regions and the Economic and Social Committee, which would probably have valuable input to this work from their different areas of expertise.
- Furthermore, the status of these guidelines remains unclear. Guidelines are by definition non-binding legally, but these guidelines are meant to set out the quality and safety standards regarding healthcare in the Member State of treatment and therefore could potentially have consequences for the assessment of a State's responsibility in eventual proceedings before the ECJ (be it in infringement proceedings or preliminary rulings). In addition, it is not evident whether the existence of such guidelines would actually provide any additional value in terms of clarity and legal certainty than the already existing Council Conclusions on Common values and principles in EU health systems[4].
- Finally, the proposed Directive leaves some implementing measures to be adopted at a later stage by the Commission through the comitology procedure[5]. The majority of the measures (i.e. list of treatments other than those requiring overnight accommodation subject to the same regime as hospital care, measures to exclude specific categories of medicinal products or substances from the recognition of prescriptions, list of conditions and criteria which must be fulfilled by European reference networks and the procedures for their establishment) are to be adopted according to the so called regulatory procedure with scrutiny (article 5a of the Comitology Decision). Since the aforementioned measures are in essence quite technical, they do indeed constitute measures aimed to supplement non-essential elements and can therefore be adopted by the said procedure. Moreover the regulatory procedure with scrutiny ensures that the European Parliament and the Council are always involved in the passing of implementing legislation and therefore provide adequate guarantee for the respect of the subsidiarity and proportionality principles.
- Other implementing measures however (i.e. the development of a Community prescription template and the support to the interoperability of prescriptions, measures to ensure the correct identification of and information on medicinal products, measures to achieve the interoperability of ICT systems in the field of healthcare) are to be adopted by the normal regulatory procedure (article 5 of the Comitology decision). Seeing that the aforementioned measures can be considered as having a certain degree of autonomy, inasmuch as they are not strictly related to the central aim of the proposed directive, their categorisation as "implementing measures" and the related consequence that they are to be enacted by the Commission through the regulatory procedure can be questioned.

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4 OJ C 146 p. 1 22/06/2006.

5 Council Decision 1999/468/EC.

- In any case the Committee could ask that representatives from regional and local authorities, which enjoy competences in healthcare, participate in the aforementioned Comitology committees.
- It should be underlined that cooperation in the field of healthcare as envisaged by the Directive and especially the creation of European reference networks, E-health initiatives, cooperation in the management of new technologies and data collection for statistical and monitoring purposes, could be effectively mounted through the legal vehicle of the European Grouping of Territorial Cooperation (Regulation 1082/2006/EC)..The EGTC project "Hospital de Cerdanya" (Regions of Cerdanya (Spain/Catalonia and France) and Capcir (France)) is an example of a project where the partners use the EGTC as a tool to legitimize and institutionalize their cross border project-initiative. The main argument is the flexibility of the system: it enables the partners to be at different levels (national, regional) and the same time it provides a useful framework for the cooperation. The EGTC is used as a means for institutionalizing the health sector cooperation of two different structures in order to become legally and financially legitimised. The project has the potential to become a symbol of innovative cross-border project-cooperation in sensitive sectors. The fact that the Cerdanya Hospital manages to overcome these obstacles and put the needs of the people in the region ahead of national politics can have far reaching effects.

4. Content of the proposal and background

4.1 Background

- *The Council*

At the 2440th meeting of the Council held in Luxembourg on 22 July 2002 the representatives of the Member States declared that it was necessary to strengthen cooperation in order to promote the best possible access to high quality healthcare services, at the same time ensuring the financial viability of healthcare systems in the European Union. The European Union's imminent enlargement means that this need is all the more urgent.

- *The ECJ*

For ten years the ECJ has been a major player which has stressed the principles of the freedom of movement (and freedom of choice) for insured persons.

Attention should be drawn to the following judgements:

- the Kohll & Decker judgment (1998) is considered to be of seminal importance as it sanctioned the reimbursement of medical treatment provided in a country in which a patient is not insured (the cases concerned dentistry and the purchase of spectacles) in accordance with the procedures and tariffs of the patient's country of origin. The Member State in which the patient is registered may still require that prior authorisation is obtained. Nonetheless, this judgement does not apply to outpatient services;

- the Smits & Peerboom judgement (2001) raised the issue of hospital services, which are much more sensitive financially. It is possible to obtain reimbursement for hospital care provided in another Member State; equally, the country of origin may impose a requirement for prior authorisation. However, this may not be refused if the patient is unable to obtain similar treatment, which is equally effective, without undue delay, in his/her country of origin;
- the Muller-Fauré judgement (2003) concerns outpatient services. It made it illegal for a patient's country of origin to impose a prior authorisation procedure. However, such prior authorisation may be maintained for hospital services;
- the Watts judgement of 16 May 2006 removed two uncertainties: the provisions on the freedom to provide services apply to all Member States, including countries where health services are financed via a system of integrated public funding (the Beveridgien method). Moreover, "the need to respect the responsibilities of the Member States for the organisation and delivery of health services and medical care (Article 152 (5) of the Treaty does not exclude the possibility that the Member States may be required under other Treaty provisions to make adjustments to their national systems of social security;
- The Stamatelaki judgement of 19 April 2007 confirms the situation regarding payment by the country of origin (in this case, Greece) for medical services provided in a foreign private clinic. The judgement does not, therefore, exclude the principle of prior authorisation, provided that its implementing provisions comply with the principles of EU law.

The financial impact of these developments may turn out to be modest; however, the ECJ's case law has made it possible to gradually extend the principle of the freedom of movement into an area which had hitherto remained the exclusive domain of the Member States. It is clearly beneficial for insured persons, as it gives them greater freedom of choice. Nonetheless, one can sense a need to define a clear legal framework for this issue, a matter which falls within the remit of not the ECJ but the European Commission, in close cooperation with the Member States. This legal certainty is necessary as much for the Member States as for the insured persons.

- *Parliament*

The European Parliament contributed to the discussions on cross-border healthcare with various reports. In April 2005 the European Parliament adopted a report on patient mobility and health care developments in the European Union[6] then, in March 2007, a resolution on Community action on the provision of cross-border healthcare[7] and, lastly, in May 2007 a report on the impact and consequences of the exclusion of health services from the Directive on services in the internal market[8].

4.2 The proposal

6 A6-0129/2005 fin.

7 B6-0098/2007.

8 A6-0173/2007 fin.

As part of the Renewed Social Agenda, the Commission adopted on 2 July 2008 a proposal for a directive to facilitate the application of European patients' rights in relation to cross-border healthcare, as well as a Communication on improving co-operation between Member States in this area.

This directive aims to provide a clear framework governing cross-border healthcare.

Its main provisions were as follows:

- patients have the right to seek healthcare abroad and be reimbursed up to what they would have received at home;
- Member States are responsible for healthcare provided on their territory;
- the directive will facilitate European cooperation on healthcare and will support the development of European reference networks by promoting the pooling of resources to tackle rare conditions;
- health technology assessment to reduce overlap and duplication of efforts in this field and hence promote the effective and efficient use of resources;
- activities in the field of "e-Health" will also be strengthened.

This proposal would not modify the existing framework for coordination of social security schemes and this framework will remain in place with all the general principles on which the regulations on coordination of social security schemes are based, including putting the patient receiving healthcare in another Member State on the equal footing with the residents of that Member State, and the existing European Health Insurance Card. In terms of patients seeking planned healthcare in another Member State, this ensures that if the appropriate care for the patients' condition cannot be provided in their own country without undue delay, then they will be authorised to go abroad, and any additional costs of treatment will be covered by public funds. The mechanism for this is already in place through the regulations on coordination of social security systems[9], and this will continue to be the case.

The new directive on cross-border healthcare would put in place an alternative mechanism based on the principles of free movement and building on the principles underlying decisions of the Court of Justice. This would allow patients to seek any healthcare in another Member State that they would have been provided at home and be reimbursed up to the amount that would have been paid had they obtained that treatment at home, but they bear the financial risk of any additional costs arising.

4.3 Previous opinions of the Committee of the Regions

In its opinion of 30 September 2004 on the Communication from the Commission on the Follow-up to the high level reflection process on patient mobility and healthcare developments in the European Union, the Committee of the Regions emphasised in particular that:

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

- one must respect the fact that the field of health services and, in particular, its organisation and funding, is the responsibility of the Member States themselves. The principle of subsidiarity must be respected;
- it is of key importance to specify the consequences of the rights of citizens, pursuant to Community legislation, to seek healthcare in another Member State and to be reimbursed for medical expenses incurred in another Member State as described in the Proposal for a Directive on services in the internal market and in Regulation No 1408/71 on the coordination of social security schemes;
- it is important to ensure that the most vulnerable patients such as, for example, older people who have no social network or patients with psychological problems are also able to exercise the rights which they are guaranteed under Community legislation. This assumes, for example, that the information will be available there where it is needed in the form of guidance and counselling services in each of the Member States;
- structured and coordinated European level cooperation for the purpose of exchanging experiences, sharing knowledge and conducting research into the development of health technologies can give the Member States real added-value in this area.

5. The procedure

Commission responsible at the Committee of the Regions: DEVE Commission
Rapporteur: Mr Karsten Uno Petersen (DK/PES)
Analysis: September 2008
Scheduled date for adoption by DEVE Commission: 16 December 2008
Scheduled date for adoption at plenary session: 10-11-12 February 2009

Inter-institutional timetable

Adoption by the European Commission: 2 July 2008
DG responsible: DG SANCO
Council: September 2008: in-depth analysis of the draft directive at the Council
Parliament: The proposal has little chance of passing through the co-decision procedure under the Barroso Commission. The first reading vote in the Parliament will take place next spring; however, after the June 2009 parliamentary elections, readings will have to start anew, a process which will involve new rapporteurs.

6. Appendix and reference texts

6.1 List of opinions previously adopted on the subject by the CoR

- CoR opinion of 30 September 2004 on the Commission Communication: *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 *Modernising 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 coordination"* COM(2004) 301 final - COM(2004) 304 final. CdR 153/2004.
- CoR opinion of 17 November 2004 on the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: *e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area* COM (2004) 356 final CdR 256/2004.

6.2 Reference texts

- Journals of the cross-border operational mission (MOT) - issue 4 on cross-border health cooperation December 2004.

- Opinion of the Association of European Border Regions (AEBR) on cross-border health care of 10 March 2006.

- HealthBASKET: Summary and recommendations regarding policies to be followed. Project financed by the European Commission as part of the 6th EU Research Framework Programme. The project took place from April 2004 to March 2007 under the direction of the European Health Management Association (EHMA).

- 2440th session of the Council – health – Luxembourg, 26 June 2002 – 10090/02 (presse 182).

- Healthcare Services in Europe in 2007: what is at stake? - Arnaud Seen - Robert Schuman Foundation – European issues n°72 – September 2007.

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Comments and additions from the Rapporteur to the Analysis Note drafted by the DEVE Commission and the Subsidiarity Unit

Additions are indicated in italic. Deletions are indicated in strikethrough.

Page 2, par. 3.1.2 : sentence deleted and replaced

There is a broad consensus among the Member States, however, that the movement of patients should not undermine the "financial balance" of national health systems within the European Union. ~~The amounts at stake in the field of patient mobility are currently small (estimated to be around 1% of national health expenditure).~~ *The amounts at stake in the field of patient mobility are estimated to be around 1% of national health expenditure.*

Page 5, 3.2.2, second bullet point : partial addition

… , but it does not consider that such an eventuality would undermine their sovereign powers in the field of healthcare. *It is a matter of concern however that the Commission on the one hand insists the EU has no competence over the way health services in the Member States are organised and provided (see Art. 152), but on the other, states that the directive enjoins Member States to make a number of adjustments to their national health care and social security systems. This creates confusion about the scope of the Commission's authority.*

Page 6 & 7, par. 3.2.3, fourth bullet point : sentence deleted and replaced

……. substantial costs for the authorities concerned, but ~~these can be judged to be commensurate to the perceived benefits from the facilitation of cross-border healthcare~~ *the Commission judges these to be commensurate to the perceived benefits from the facilitation of cross-border healthcare.*

Page 6 & 7, par. 3.2.3, fifth bullet point : partial addition

It can be observed that the impact assessment presented by the Commission only marginally addresses the possible territorial impacts of the proposed directive, *and it is not clear whether the costs which the affected authorities will face in implementing the directive will be commensurate with the directive's benefits.*

Page 6 & 7, par. 3.2.3 : addition of a sixth bullet point

For this reason, health authorities should be able to turn down patients for capacity related reasons, and to make the right to reimbursement for treatment received in another EU Member State contingent on prior approval. This is to ensure economic balance and the ability to plan are maintained in Member States' health care systems.

Page 8, par. 3.2.4 : addition of a third bullet point

It should also be pointed out that the introduction of common quality and safety standards could constitute an infringement of Article 152, since these would have a bearing on Member States' ability to organise and provide health care services freely.

Page 11, par. 4.1 : addition

….provisions comply with the principles of EU law.
The financial impact of these developments ~~is~~ *may turn out to be* modest.