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ASSOCIATION INTERNATIONALE DE LA MUTUALITE

Implications of recent jurisprudence on the co-ordination of health care protection systems

Summary Report

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EXECUTIVE SUMMARY

The judgements of the **Court of Justice of the European Communities (ECJ**) in the *Kohll* and *Decker* cases have evoked a lively reaction and created keen interest among managers of health care systems and a number of other actors in the health care field. Although the facts of these cases are relatively simple, they raise some major issues, including: access to health care, "marketization" of the health care sector, patient mobility within the EU, freedom of movement for medical goods and services, the co-ordination of health protection systems and their regulatory mechanisms, cross-border treatment and related experiments in the field of easing access to health care abroad and reorganising medical resources in border regions.

The importance of *Kohll* and *Decker* for the health care sector is reflected by the growing number of cases pending before the ECJ that seek some clarification of the issues raised in these two seminal judgements. All these cases raise major questions regarding the relationship between the principles of the internal market as defined by the Treaty on the one hand and the national social protection mechanisms as organised by the Member States on the other. These issues are developed at length in the general report, an outline of which shall be presented below. The final report adopts an exploratory approach and is based upon the study commissioned by the Employment and Social Affairs Directorate-General of the European Commission from the 'Association Internationale de la Mutualité' (AIM) on the implications of the recent case law concerning the co-ordination of health care protection systems.

1. In theory, there are no barriers within the EU to access to medical treatment in another Member State. However, social security coverage for the costs of this care depends upon the EC co-ordination mechanism of social security systems (contained in Regulations 1408/71 and 574/72) and is subject to certain conditions. These conditions consequently restrict patient mobility.

2. Patients usually seek medical services near their home and in a cultural environment with which they are familiar. Therefore - leaving emergency cases aside - the demand for cross-border care mainly exists in border areas and for treatment of specific pathologies. Whereas, free movement of medical goods (e.g. pharmaceuticals) may be spurred on by a real transparency in prices and quality levels, as well as by a growth in selling at distance.

3. In view of the diversity in health care systems within the EU, it is essential for (medical) consumer protection that patients should have all the necessary data required to make an informed decision about going to another Member State to receive medical goods and services. This data includes accurate information about the price, the extent of their social security coverage, the quality of care, the medical competence and practices they might expect.

4. The judgements in *Kohll* and *Decker* have established a dual system in which patients have a choice of two possible procedures for coverage of health care abroad. Some countries are implementing this new method (although often limiting it to outpatient care), while others are not doing so. Most Member States believe that they are not affected by the rulings and claim that the principles enunciated therein apply only to health care systems that use reimbursement schemes (Luxembourg, Belgium, France). Their greatest fear is not really a mass exodus of patients into or out of their countries but rather the potential internal effects on their own systems (e.g. cost containment policies, quality control measures, exclusive contracting between social security institutions and health care providers)

5. There are some important differences between the new procedure developed in "*Kohll* and *Decker*", stemming from the free movement of goods and services, and the existing one found in

the co-ordination regulations based on the free movement of workers. According to the first one the patient travels to another Member State where s/he pays a health care provider directly for his/her treatment before returning home and claiming a reimbursement of the cost of the services "*as though they were provided in his or her country of residence*". Under the second one a patient having received a prior authorisation for foreign medical care, is integrated into the social protection system of the country in which the service is provided, "*as if he or she was insured with it*".

6. The judgements in *Kohll* and *Decker* left many questions unanswered. They mark a break in the uniform approach to access to cross border care within the EU. This could result in inconsistent practices, administrative and legal uncertainty as well as unequal treatment among Member States or even citizens in any one country. Some actors may play a decisive role as regards defining the sphere of possible action in the field of cross-border care and the European dimension which will be developed in the fields of health care and social security coverage by:
   - the case law of the ECJ in the cases already pending and those that will inevitably arise in the future;
   - the capacity of Member States to develop health and social protection policies suited to the needs of their populations that are compatible with European integration;
   - the pressure from public opinion and, even more, from some actors favouring the establishment of an internal health care market;
   - the Community's policy options regarding a social Europe, especially in the field of social protection.

7. The first priority is to clarify the current situation and remove the prevailing insecurity. It would appear essential to accompany and extend the ECJ process. At a national level, it will be for the political decision-makers to make their health care protection systems "Euro-compatible". At Community level, an interpretative communication concerning the application of the free movement principles to health care protection would clarify the reasoning adopted by the ECJ with a view to extending it to other situations and systems.

   To the extent that medical goods and services are affected by the application of the principle of freedom of movement, the criteria established by the social protection systems (personal and material scope, as well as scope of implementation) may not directly or indirectly discriminate against foreign providers or suppliers without justifiable cause.

8. The procurement system, i.e. the way of purchasing medical services and goods in the field of social health protection, appears as a key factor for a good understanding of the rulings. Even if much of the academic, political and legal debate surrounding the application of *Kohll* and *Decker* has centred upon the traditional distinctions between reimbursement systems and systems involving benefits in kind, it is clear that the judgements in *Kohll* and *Decker* might have implications for every type of health care system. If so, the non-discrimination principle applied in the context of cross-border care could mean that:
   - a health care provider may not be prevented from joining the contractual system of another Member State on the sole grounds of nationality or place of establishment, but only on the basis of legitimate, objective and proportional criteria;
   - where a social protection system also reimburses services provided by non-contracted practitioners established on its territory, it may not exclude those of (non-contracted) providers in another Member State.

9. A proactive policy approach on the part of Member States, supported by the Community bodies, would make it possible to develop a dynamism improving the conditions for access to care as well as the effectiveness of health care systems, especially in border areas and for the benefits of people residing there. While respecting the conditions specific to each border region, the Commission

could take initiatives with a view to co-ordinating and giving an impetus to activities along these lines (recommendations, action programmes, regional observatories etc.).

10. Technological and scientific developments in the field of health care are leading towards more concentration of medical know-how, financial resources and facilities in centres of excellence. These hospital centres are developing a European and even international strategy. With a view to facilitating access to these centres for the benefit of all EU citizens, the Commission could encourage Member States to prepare an operational framework guaranteeing fair financing, financial accessibility and quality of care.

11. Although Regulations 1408/71 and 574/72 allow Member States to conduct a restrictive policy in the matter of authorising treatment abroad, they in no way oblige them to do so. In this way the *Kohll* and *Decker* rulings and their wide response in public opinion could be an incitement for Member States to ease their authorisation criteria. Nevertheless, in the light of sometimes alarming waiting lists, the co-ordination mechanism appears to offer patients a remedy against rationing policies that would adversely affect their state of health and their basic right of access to care. Indeed authorisation for treatment abroad may not be refused if the treatment is covered by their health care scheme and cannot be provided within "*the time normally necessary*" (Article 22(2)(2)).

    To resolve the legal and administrative uncertainty caused by the judgements in *Kohll* and *Decker* one might consider integrating the new procedure into Regulation 1408/71 as a subordinate procedure or possibly into Article 34 of Regulation 574/72.

12. In addition to the proposals to make the rules governing access to cross-border treatment more flexible and to extend the scope of Regulation 1408/71 to all persons insured under social security schemes (including third-country nationals), it would seem appropriate to review its managerial procedures with a view to easing the administrative burden and controlling flows more effectively. In this context, it is essential to establish the statistical methodology that is currently sadly, lacking. Such a methodology is vital as any effort at analysing patient mobility and its impact on health care protection systems runs up against this deficiency.

13. The Commission and the Council have recently launched a new Community strategy aimed at establishing closer co-operation between Member States in the field of social protection on the basis of four key objectives, one of which is "to *ensure a high and sustainable level of health protection*"[1]. This strategy should include access to health care in general and to cross-border care in particular within its scope. With the support of the European Parliament and with a view to including a right to health in the revised EC Charter of Fundamental Rights, the Commission could clarify and give specific content to the idea of the general interest in the field of social protection relating to health care so that the rules of the internal market will produce only positive and desired effects.

14. The quality of health care and health safety need just as much attention at Community level as do food and environmental safety. Contrary to what was advanced by the ECJ in *Kohll* and *Decker* the quality of care is by no means guaranteed by the mutual recognition of diplomas, which primarily covers mobility for health professionals. The new Community strategy defined in the field of public health[2] could provide a firm basis for initiating a common reflection on a non-binding frame of reference for quality standards, the criteria for good medical practices, the rules governing the equivalence of medical skills and services, hospital accreditation etc. In the context of enlargement, it is essential that the European Union should have an instrument of this nature.

[1] Communication of the European Commission, *A concerted strategy for modernising social protection* (COM (199) 347 final of 14 July 1999); Council Conclusions of 17 December 1999 on strengthening co-operation with a view to modernising and improving social protection, OJ C 8, 12 January 2000, pp.7-8.

[2] Communication of the European Commission concerning the European Community's health strategy, *Proposal for a Community action programme in the field of public health (2001-2006)*, COM (2000), 285 of 16 May 2000

15. As any steps taken in the health sector require the participation of the various actors (e.g. social security institutions, mutual health funds, health professionals, health care institutions, organisations representing patients etc.) it would be appropriate to bring them together in one forum for the purpose of exchanging views and discussing all the problems relating to health, health care systems, access to care, quality of care etc. An initiative of this nature at Community level should serve as an incentive for the preparation, in the long-term, of an effective balance between the EC rules on the internal market on the one hand and the organisation of the national social health care systems on the other.

INTRODUCTION

Access to health care abroad and patient mobility have generated much debate since the **Court of Justice of the European Communities (ECJ)** overturned the Luxembourg regulations defining the procedure for cross-border social health care[3]. Those regulations made the coverage by social security for medical treatment given in another Member State, in this case orthodontic treatment and the supply of spectacles, subject to prior authorisation. For the ECJ, these stipulations in Luxembourg law constituted infringements of the principles of the free movement of goods and services, which were held to apply to national social security systems.

These judgements have given rise to a variety of reactions. The Press has virtually unanimously welcomed them as a social improvement for patients, a step forward in the rights of European citizens and a positive advance in the process of creating an internal market in health care. The Member States see the decisions of the ECJ as undermining their competence to organise their system of social protection and health care according to their own choices, rules of operation and criteria defining access to care and controls on the quality of care. The majority of Governments also consider that unlimited access to health care abroad would jeopardise policies to contain costs, efficiently allocate resources, as well as public health policy. Finally, the social security administrations responsible for implementing the rules governing coverage for cross-border care consider that the rulings are a source of administrative complication and legal uncertainty.

The importance of the *Kohll* and *Decker* judgements and the cases currently pending before the ECJ goes beyond the simple problem of cross-border care. The rulings actually affect the relationship between the economic freedoms guaranteed by the Treaty structuring the internal market (also in the field of health care) on the one hand and the foundations of social protection (ensuring access to health care) organised on a national level on the other.

There has been much discussion about the scope of the judgements and their short and medium-term consequences. In the near future, cases pending before the ECJ should partly clarify certain questions which have not yet been resolved. A number of Member States have, however, reiterated that it is not up to the ECJ to drive policy in this area. Consequently it is not unlikely that some Member States or Community bodies may take political action in order to channel or stem the tide of any unexpected and undesirable effects of the infiltration of EC economic rules into the social domain at national level.

This report intends to:

- put the *Kohll* and *Decker* judgements back in the context of access to care organised within the European Union;
- outline the current state of the debate within the Member States and among different actors in the health care sector;
- evaluate the implications of the *Kohll* and *Decker* judgements on health care systems and access to care;
- work out action scenarios and political options with a view to reconciling the principles of the free movement of goods and services and the competence of the Member States to organise their own social protection and health care systems, while pursuing the aim of achieving a high level of social protection and health care[4].

[3] ECJ, 28 April 1998, *Decker*, C-120/95 and ECJ, 28 April 1998, *Kohll*, C-158/96 ;
[4] For the methodological approach, we would refer the reader to the general report.

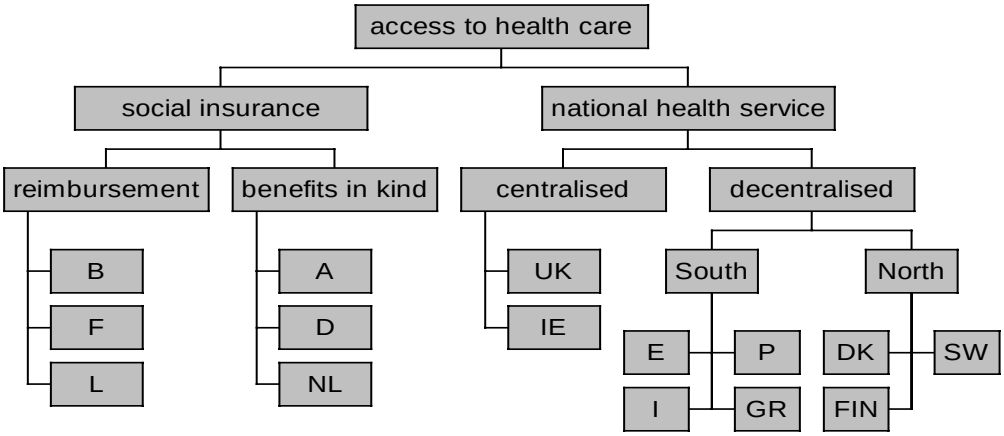
PART 1: THE CONTEXTUAL FRAMEWORK

1.1. The organisation of access to care in the European Union

Within the European Union, the areas of social protection and health care have always been considered as falling virtually exclusively within the competence of the Member States. Although, since the Treaties of Maastricht and Amsterdam, the achievement of a high level of social protection and health care has been established as one of the aims of the Union[5], the competencies attributed to the Community level are still limited[6].

The Member States of the European Union are characterised by their social model of protection against social risks. Historically, the systems of access to health care which are in force today have their roots in the early days of the industrial revolution. The current forms of organisation and financing of these systems are essentially based on two separate structural ideas: compulsory social insurance on the one hand and the national health service on the other. They are sometimes also called the Bismarckian system and the Beveridgian system respectively, in honour of their founding fathers.

Typology of public health care systems in the EU



- Compulsory health insurance systems implement categorial protection (often extended to cover the whole population of a State), funded through social contributions and managed by the social partners. Some of them (B, F, L) reimburse (outpatient) services [7]. These reimbursement systems are usually also characterised by freedom on the part of the patients to choose their provider. Other States (A, D, NL) guarantee access to health care through direct provision of benefits in-kind, offered by medical providers contracted by health insurance bodies. In this case, the patient's freedom of choice is limited, particularly since more specialised care is usually subject to referral. On the other hand, patients' contributions are often lower.

[5] The Community's mission is to promote "a high level of social protection" and "to enhance the standard of living and the quality of life" (Art. 2 of the Treaty instituting the European Community) through "a policy in the social domain comprising a European Social Fund" (Art. 3,1, j), "reinforcing economic and social cohesion" (Art. 3,1,k) "and helping to bring about a high level of health protection" (Art. 3,1, p).

[6] For an overview of the Community's competencies in the area of social protection and health care, see the general report (part 1, I, 2);

[7] In the case of hospital care and other expensive services, these countries generally apply a system called third party payer, i.e. payment for the services is made directly to the providers by the insurance bodies.

- National health services provide universal protection to all the residents of a country, by directly organising medical services, often of a public nature, which are financed mainly by tax revenue. Generally medical services are free of charge, except for some fixed payments. In return, patients are obliged to receive treatment from the health care providers in the public system and/or from those contracted by it. There are various levels of organisation within these systems, ranging from centralisation to decentralisation[8].

Despite these essential differences, it should be stressed that all health care systems have undergone considerable development over the past two decades. Each model is inspired by the management and financing techniques of the others and all the systems are striving to face the same challenges[9]. There is consequently a tendency towards convergence of the different health care systems, which are all moving towards 'mixed systems'[10].

One should not, however, deduce from this statement that there are prospects for harmonisation[11]. Harmonisation is unlikely since disparities in the area of health care and social protection are also seen on other levels:

- the resources available to health care systems vary considerably from one country to another, essentially in accordance with the economic capacity of that country;
- the mechanisms for the allocation of resources are structured in accordance with the social, political, economic, institutional and legal history, and also the demography and geography of each State;
- the heterogeneity of medical practices and medical consumption are most often based on infrastructural factors and the availability of treatment and technical equipment as well as the level of human competence available;
- the state of health of the population and inequalities in this regard can be seen both between States and also within each country.

1.2. Access to care outside the State of affiliation

1.2.1. General principles

In theory, there are no borders for those wishing to receive health care in another Member State, if they are resident within the EU and they are entitled to freedom of movement. Initially the free movement of persons was limited to workers. Gradually it has been transformed into a right of European citizens[12]. Nevertheless, the right to reside, which is given to all European citizens (including students, pensioners and unemployed people) is still subject to two conditions: to be properly covered by a health insurance system and not to be a burden to social assistance in the host country[13].

[8] For a summary of the main characteristics of the systems, consult the general report (part 1, chapter II, 2);

[9] The most striking phenomenon seen in the past four decades is that of the rapid increases in health spending in all industrialised countries. This is expressed by a virtual doubling of the proportion of gross domestic product (GDP) devoted to health care, hence the need for a policy to control health spending.

[10] On the convergence of health care systems, cf. Recommendation of the European Council on the convergence of the objectives of social protection policies, 92/442/EEC dated 27 July1992, OJ, 1992, L 245/49.

[11] The harmonisation of social protection systems is not one of the aims of the process of European integration. It is, however, expected as a long-term development that would follow from the operation of the common market, as stated in Article 136, 3 of the Treaty.

[12] Article 18 of the Treaty, integrated in the Single Act, stipulates: *"Every citizen of the Union has the right to move and reside freely within the territory of the Member States, subject to the limitations and conditions set out in this Treaty and the measures taken for its implementation"*

[13] Council Directives 90/364, 90/365, 90/366 dated 13 July 1990, O.J. 1990, L 180/26 and Directive 93/96, O.J. 1993, L 317/59;

Traditionally, health care systems governed by the Welfare State limit financial cover for health care services to treatment provided within that country's territory. This territoriality principle is based on the idea of "the nation state", whose mission in the area of health care is to safeguard public health, to organise a system of care accessible to the population and to ensure that the general state of health improves. Its competence is limited to the national territory and to its own citizens.

Fearing that the free movement of labour force would be severely hindered if social security entitlements in general would stop at the border, the signatories of the Treaty of Rome created a legal basis setting up a Community mechanism for the co-ordination of social security systems. This allows migrant workers and the members of their families to receive health care in their new country of residence and also during any temporary stays abroad (holidays, family reunions etc.).

The system of co-ordination in the area of social security is governed by EC Regulations 1408/71 and 574/72[14], they are based on Article 42 of the Treaty, which governs the free movement of workers. Overall this system:

- determines the competent legislation (or state of affiliation) governing social security rights, usually that of the country in which the professional activity takes place;
- guarantees social security rights by aggregating periods of insurance, employment or residence established in other Member States;
- eliminates all discrimination based on nationality or place of residence;
- enables export of some social security benefits.

In the area of health care, application of the co-ordination regulations covers virtually the entire European population. The main exception is third-country nationals, who are excluded even if they are resident in the European Union and affiliated to a national social protection scheme.

The primary aim of co-ordination between social health care protection systems is to ensure access to care in the State of residence for migrant workers and their dependants (Art. 18-20) [15]. The right of access to health care in the State of residence is provided by means of a form E106, which is given to the socially insured person by the (previous) State of affiliation.

1.2.2. Maintaining the right of access to health care outside the State of residence

The aim of the co-ordination scheme is not absolute mobility for patients. Access to health care outside the State of residence is actually subject to certain conditions. Article 22 of Regulation 1408/71 essentially refers to two clearly distinct situations:

- **Temporary stay (Art. 22, 1, a):** a person temporarily staying in a Member State other than the State of affiliation, either for private or professional reasons, who requires immediate medical attention, can receive treatment on location at the expense of the competent State[16]. This right of access to care in the State of stay is certified by a form E111 which is issued by the competent health insurance institution. On the basis of this form, care is provided according to the legislation

[14] Consolidated version: Council Regulation (EC) 118/97 dated 2 December 1996, modifying Council Regulation (EC) 1408/71 dated 14 June 1971 on the application of social security plans to workers, self-employed people and members of their families relocating within the Community and Council Regulation (EEC) 574/72 dated 21 March 1972 defining the procedure for the implementation of Regulation (EEC) 1408/71, O.J. L 28, 30 January 1997;

[15] As for frontier workers (those who return to their State of residence every day or at least once a week) they have access to two health care systems, that of the State of residence and that of the competent State (where they work). Except where there is a bilateral agreement, this right does not extend to members of their families. Cross-border workers lose this double access upon retirement.

[16] A pensioner entitled to a pension under the legislation of one or more Member States is not submitted to the condition of urgency (immediately necessary care) to receive coverage for his health care during a stay outside his state of residence (Article 31).

of the State of stay, and then reimbursed by the competent institution according to the tariffs applicable in the Member State where treatment was provided[17].

- **Planned care (Art. 22, 1, c):** when a worker or a member of his family wishes to receive care in another Member State, he must obtain prior authorisation from his competent health insurance institution and present it to the institution in his State of stay. Form E112 certifies his right of access to care in the State of affiliation and agreement by the competent institution to cover the costs relating to the specified medical treatment.

  Although the Member States have a considerable margin of discretion when it comes to determining their authorisation policy[18], Article 22(2)(2) expressly states that authorisation may not be refused when:
  a) the treatment required by the interested party is part of the health care package covered by the social protection system in the area of health care; **and**
  b) this treatment cannot be given to him in his State of residence within the period that is normally necessary, in view of his current state of health and the probable course of his disease.

  This actual version of Article 22(2)(2) is the result of an amendment brought about by Regulation (EEC) no. 2791/81[19], following the judgements of the ECJ in the *Pierik* cases[20]. The previous version obliged Member States to grant the E112 form *"when the treatment in question cannot be given to the interested party in the territory of the Member State in which he lives"*. On this basis, the ECJ recognised a right to all medical provision that is a necessary and effective treatment of the illness or condition, even if that treatment is not covered by the health insurance system in the home State[21]. In order to extend the power of discretion given to Member States in the area of the authorisation of care abroad, Article 22(2)(2) was amended to its current version.

Based on the principle of equality of treatment, services outside the State of residence are provided to the person relocating to another Member State as *"if he were affiliated there"*. This implies that the tariffs of the State providing the treatment are applicable and that the patient will have to pay the same co-payments as an insured national from the state of treatment. Consequently the patient must comply with the conditions and procedures provided for by the providing State's social protection system in order to benefit from its health care coverage.

[17] In cases where the formalities have not been fulfilled during the stay, Article 34, 1 of Regulation 574/72 allows for the possibility of reimbursing charges incurred, at the request of the interested party upon his return. In some cases the State of affiliation may reimburse according to its own tariffs (Art. 34(4) and (5)).
[18] For a summary of the authorisation procedure and the criteria for the evaluation of the demand, see the General Report (part 1, chapter II, 2);
[19] Council Regulation (EEC) no. 2793/81 dated 17 September 1981, modifying Regulation no. 1408/71 and Regulation no. 574/72 setting the arrangements for implementation of Regulation no. 1408/71, O.J., L 275;
[20] ECJ, 16 March 1978, *Pierik* I, C-117/77 and ECJ, 31 May 1979, *Pierik* II, C-182/78 ;
[21] VAN DER MEI, The European Court of Justice and the co-ordination of health insurance schemes, in Health care without frontiers within the European Union? Free movement of goods and services in the health care sector, Documents from the international Symposium, Luxembourg, 18 November, AIM, 1998, 20 ;

1.3. The importance of cross-border health care

In 1990 a study was conducted analysing the implementation of the EC regulations in the area of health care and cross-border flows of care[22]. Although its results unavoidably under-estimated the actual flow of patients[23], it showed that the financial impact of cross-border care within the European Union was very marginal.

This observation is confirmed year after year on the basis of the financial reports produced by the Audit Commission for the Administrative Commission[24]. On average, cross-border health care within the context of this co-ordination system accounts for between only 0.3% and 0.5% of total expenditure on health care, or barely € 2.00 per inhabitant [25].
The situation of the Grand-Duchy of Luxembourg is, however, atypical. The average cost to each inhabitant of Luxembourg is € 116.00, or 9% of public health spending. This situation is principally accounted for by the limited medical infrastructure in this small State, which results in a much greater use of authorised health care abroad than in the other Member States.

At present France is the country with the highest proportion of claims (~ 40%). This position is due not only to the flow of labour and tourism related care, but also to the attractiveness of the French health care system[26]. After France, it is the countries of the South which are "importers" of patients, particularly Spain, which holds the highest proportion of flat rate claims. This would support the hypothesis that these are mainly medical expenses provided to European residents in receipt of a retirement pension from another Member State (for whom the competent states pay an annual flat rate amount). The attractiveness of these countries is therefore more due to tourism than medical reasons[27].

More detailed analysis of the policies on the authorisation of health care abroad reveals a limited use of cross-border care. Although a number of Member States are not capable of providing precise information, the number of authorisations seems to be very low. In 1999, the number of E112's for Austria was estimated to be 850, for Denmark it was only 40 to 50, for Sweden it was about 20. France had the most detailed table, with 789 authorisations and 451 refusals over a period of four years (1996-1999).

In general, the competent institutions refuse authorisation for treatment in another Member State when that treatment is also available in the State of residence. According to the 1990 survey, despite the restrictive policy, planned health care (E112) accounted for almost 60% of the total cost of the co-ordination system in the area of cross-border care. On the other hand, care provided as a result of professional and extra-professional mobility (E106 and E111) represented a heavier administrative burden in terms of the forms to be managed.

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[22] ASSOCIATION INTERNATIONALE DE LA MUTUALITÉ, Cross border health care within the European Community, April 1991, 190 p , study carried out for the European Commission, D.G. V (social affairs and employment);
[23] Not only because it does not include the amounts covered by private insurance companies which are complementary or substitutional to the social protection system as well as amounts paid directly by private individuals, but also because a number of Member States have concluded agreements whereby they waive claims for care provided in their territory to those affiliated to the social security systems of other Member States.
[24] For a more detailed summary, the reader should refer to the General Report.
[25] HERMESSE J., The opening of frontiers to patients. What economic consequences? in Health care without frontiers within the European Union? Free movement of goods and services in the health care sector, Documents from the international Symposium, Luxembourg, 18 November, AIM, 1998, 49-58;
[26] The 1990 study already showed that France was an attractive country for planned care (E112). At that time it held 78% of the total claim generated by authorised care (E112). A more detailed analysis revealed that these flows of foreign patients were mainly aimed at hospital centres situated in the Paris, Lyon and Marseille areas.
[27] On the debtor side, Italy has always been a major "exporter" of patients: 37% of the global debt of the Member States was borne by Italy, and in the case of authorised care (E112) the percentage was 74% (1990)!

1.4. Factors determining patient mobility

Should the restrictive policies of the Member States in the area of prior authorisation be seen as accounting for the marginal impact of the co-ordination policy in the area of health protection, or should we take the view that the demand for treatment abroad is particularly low among European citizens[28]?

Clearly, patients are primarily looking for treatment close to their home. In the case of primary health care services, factors such as: language, distance, the lack of information on the care provided abroad and the administrative burden of the procedures involved can be seen as objective obstacles to access to cross-border care. Even in places where certain categories of people have had free access to two health care systems for several years, it is observed that the movements of patients are very limited[29].

Taking these various factors and the specific characteristics of "health care goods or services" into account, spontaneous movements of patients seeking health care abroad seem to be limited to:

- border areas, when the proximity of the foreign medical supply, its cost, its reputation, the language, the administrative procedures and knowledge of the supply etc. favour this medical migration;
- highly specialised services where the seriousness of the treatment and the quality or even reputation of the provider are determining factors in the patient's choice.
- medical interventions for which swift accessibility cannot be guaranteed in the State of residence, particularly due to the existence of waiting lists;
- patients who have access to the information necessary to make a rational, well-informed choice;
- medicines or other medical products for which comparisons between price and quality are possible or which can be purchased remotely.

However, the propensity of patients to make use of health care provided abroad is not only determined by individual reasons. Other players who have a growing role in "the European health care market" influence the patient's choice. The first among these are the care providers, who are better informed about the capacity of the supply of care in health care systems and are seeking to take up their own positions in this market. On the other hand, health insurance bodies, the second most important player, seek to offer the best services to their 'clients' at the lowest cost, primarily within the national territory but why not abroad as well?

1.5. The *Kohll* and *Decker* judgements and the cases pending before the ECJ

In *Kohll* and *Decker* the ECJ awarded two Luxembourg citizens the right to obtain reimbursement for health care services (orthodontic treatment and the supply of spectacles respectively) provided in another Member State (Germany and Belgium) on the basis of the reimbursement tariffs applicable in their State of affiliation (Grand-Duchy), without prior authorisation having been given by these individuals' health insurance fund.

[28] Factors influencing the patient's choice of a medical service or product are the seriousness of the treatment, the proximity of the treatment location, the quality or reputation of the provider or hospital establishment, the waiting period, confidence, communication, the cost of care, the procedure associated with reimbursement of care and knowledge of what is available abroad among national providers.

[29] CALNAN, PALM, SOHY and QUAGHEBEUR, Cross-border use of health care. A survey of frontier workers' knowledge, attitudes and use, European Journal of Public Health, 1997, no. 3 suppl., p. 26-32;

The ECJ argued:

- that the Member States have the power to organise their social security systems (*Decker* 21-22; *Kohll* 17-18);
- that nonetheless, social security provisions are not exempt from the application of the basic principle of free movement (*Decker* 24-25; *Kohll* 20-21);
- that article 22 of Regulation no 1408/71, which also requires prior authorisation for coverage of care provided in another Member State on behalf of the competent institution but according to the tariffs in effect in the State where the care was provided, does not prevent reimbursement at the tariffs in effect in the State of affiliation in the absence of prior authorisation (*Decker* 27-29; *Kohll* 25-27);
- that the prior authorisation requirement discourages insured persons from seeking care from service providers or suppliers of medical goods established in other Member States and therefore constitutes a barrier to the free movement of patients (*Decker* 34-36; *Kohll* 34-35);
- that in this instance, the requirement for prior authorisation could not be justified, either on the basis of a serious threat to the financial balance of the social security system, or for reasons related to public health (protection of the quality of medical services, maintenance of a medical and hospital service that is balanced and accessible to everyone) (*Decker* 40-43; *Kohll* 40-42, 47, 52).

Meanwhile, further cases have been brought before the ECJ:

- In the *Vanbraekel* case[30], prior authorisation (E112) for an orthopaedic operation carried out in France was refused by the Belgian mutual health fund in question because the request was insufficiently motivated. The transferring judge, having already ruled that it was illegal to refuse authorisation, made a preliminary ruling to the ECJ concerning the applicable reimbursement tariffs. The *Vanbraekel* family is actually claiming that Belgian tariffs should be applied (leading to higher reimbursement than the French ones), and is referring explicitly to the *Kohll* judgement.
- In the *Geraerts-Smits*[31]case, Mrs *Smits*, who suffers from Parkinson's disease, was refused a categorial and multidisciplinary treatment in a hospital in Kassel (Germany) on the basis that this treatment does not offer any additional advantage in relation to the sufficient and adequate treatment that can be provided, in good time, by a contracted provider in the Netherlands.
- In the *Peerbooms* case, a comatose patient was refused authorisation to undergo an intensive neurostimulation therapy treatment at the University Hospital in Innsbruck (Austria) but was taken there anyway. Even if this treatment proved to be particularly effective, in the Netherlands it is considered to be experimental and does not fall within the material scope of the Dutch statutory health insurance[32].
- In the *Müller-Fauré* case[33], a Dutch insured person deliberately requested dental care during her holiday in Germany, allegedly because she was not satisfied with the care provided by Dutch dentists. She was refused reimbursement by her health insurance fund for the primary reason that the treatment administered was not urgent.
- In the *Van Riet* case, Mrs *Van Riet* went to a Belgian hospital for an arthroscopy, without suffering the inconvenience of the Dutch waiting lists. She did not request authorisation for care abroad from her health insurance fund until she returned to the Netherlands. She was refused this authorisation on the basis that sufficient and adequate care could have been given to her in the Netherlands and that there was no medical necessity to justify the treatment received in Belgium.

The Advocates-General have filed their opinions to the ECJ in the *Vanbraekel* and *Smits/Peerbooms* cases. The two cases are situated in two different contexts: that of a (Belgian) reimbursement system on the one hand and a (Dutch) system of benefits in-kind on the other. In general, they both seem to

[30] Case C-368/98, *Vanbraekel/Alliance nationale des mutualités chrétiennes (ANMC);*

[31] Cases C-157/99, *Smits (wife of Geraets)/Stichting Ziekenfonds VGZ and Peerbooms/Stichting CZ Groep Zorgverzekeringen*;

[32] In the Netherlands this type of treatment is only covered by statutory health insurance on an experimental basis at two Dutch medical centres, to which *Peerbooms* did not have access because these experimental treatments are reserved for patients less than 25 years of age. For *Peerbooms*, only traditional treatment in a rehabilitation centre could be paid for.

[33] Case C-385/99, *Müller-Fauré* and *Van Riet*;

defend the idea that medical services, which form an integral part of the public health care system and are financed from public funds, are not remunerated services. Consequently, they do not fall within the scope of the free movement of services[34]. In the Dutch cases, the Advocate General seems to deduce this view from the organisational characteristics of the system of benefits in-kind[35]. In the Belgian case, it is more difficult to assess whether the view of the Advocate General on the non-remunerative nature of the medical service relates to only hospital care or whether it extends to the whole reimbursement system.

1.6. Conformity of administrative practices to the judgements

The judgements of the ECJ in the *Kohll* and *Decker* affairs have given rise to very diverse reactions from the main players involved the field of health care and health care protection and depending on their own ambitions and interests, they advance either restrictive or extensive interpretations of them[36]. Although some virulent political reactions were expressed immediately after the rulings were given, no joint action has been taken by governments to alleviate the possible implications of these rulings. The majority of Member States have pursued their restrictive policy in the area of health care abroad on the basis of the view that the rulings are only applicable to reimbursement systems. However, it appears that some of these in-kind benefit systems or national health services actually pay the full amount of unauthorised medical services provided abroad, when asked to do so by an insured, just to avoid court cases that might attract the attention of the public.

- Luxembourg and Belgium have set up administrative procedures in order to provide unconditional reimbursement for medical treatment and goods provided in another Member State when outpatient services are involved[37]. The initial indications are that the financial impact of these new *Kohll* and *Decker* procedures is limited[38].
- Prior to the rulings, the Austrian system already provided for reimbursement of services dispensed by a non-contracted provider, either in Austria or abroad, amounting to 80% of the amount paid to a contracted provider. The annual number of reimbursements for private services provided outside Austria (not limited to the EEA) would be about 58,000 for a sum of ATS 47 million (€ 3.4 million), or an average cost of € 58 per case (compared with € 5,523 per E112 issued by Austria). This method of using cross-border health care is mainly used in border areas and for outpatient care.

  This system of cover has been used more frequently since the fall of the iron curtain, particularly for dental care partly covered by statutory health insurance, i.e. many Austrians going to Hungarian dental practitioners[39] . When this movement of patients began to take place, the Austrian health funds at first refused to reimburse them, referring to the difference in the quality of care provided by Hungarian dental practitioners in relation to the Austrian criteria. This argument, however, was rejected by the Austrian Supreme Court (Oberste Gerichtshof)[40].

[34] The two Advocates-General refer to the *Humbel* ruling (ECJ, 27 September 1988, *Humbel*, 263/86).

[35] On a subordinate basis, the Advocate-General defends the position that any possible obstacle to the free movement of services can be justified by the need to maintain the financial equilibrium of the compulsory health insurance system, to guarantee a balanced medical and hospital service which is equally accessible to all those affiliated to it and to maintain the necessary health care capacity and medical competence within the national territory, given that it applies without discrimination to national providers of medical services and those established abroad and that it is necessary and proportionate in order to guarantee the aims that it is pursuing.

[36] For a detailed analysis of the position of the Member States and the main players in the field of health care and social protection, see the general report (Part 1, Chapter III, 3-5);

[37] Belgium has set a ceiling for the amount of the reimbursement at € 1000 per trip.

[38] In Belgium, the cost of this new procedure would have been € 25,000 in 1999. For Luxembourg, reimbursement according to the *Kohll* and *Decker* procedure would represent 0.5% in relation to the same type of services provided in Luxembourg.

[39] Statistical details from the Niederösterreich health insurance fund (Niederösterreichische Gebietskrankenkasse) prove the importance of dental care in PECOs : out of 4,715 cases, 1,360 involved reimbursement for dental care, 1,200 outside EU and EEE countries.

[40] At the time it was considered that reimbursement for services provided by Hungarian dentists would have a deflationary effect on the high rates charged by Austrian dentists, but this has not happened.

- Instead of claiming that the rulings are not applicable to their system of benefits in-kind, the Danish government analysed its system according to detailed criteria, focusing on the level of commercialisation of the services covered by compulsory health insurance[41]. On the basis of this analysis, an amendment of the law on national health insurance and the law on social services was filed in February 2000, stipulating the reimbursement of a limited series of outpatient services (medicines excluded) delivered or provided in EEA countries. This legal amendment should come into force from 1 July 2000.
- In Finland, the statutory health insurance fund has adapted the way it reimburses the cost of private treatment in accordance with the judgements. In 1998, the Social Insurance Institute modified its instructions to local social security authorities concerning the implementation of statutory health insurance with regard to covering the costs of care provided in another Member State. Since then reimbursement is provided unconditionally for health care covered by this legislation and obtained in any Member State.
- In Greece, the existing reimbursement schemes for employees of banks and other legal entities governed by public law and for professionals are already applying the principle of reimbursement of services abroad on the basis of the Greek tariffs. These practices seem to be considered to be in accordance with the rulings.

1.7. The "fear" of the internal implications to health care systems

In their reactions, the Member States were particularly concerned about the potential scope of the decision by the ECJ. Apparently, this concern is not particularly focused on a massive flow of patients abroad, at least not for the Member States in Northern Europe. The “fear” currently being expressed by the Member States rather relates to the implications of the rulings on the organisation, operation and management of their health care systems. The jurisprudence of the ECJ could have an impact on various levels.

- What is the risk that the basic principles of the systems could be affected by the implementation of European principles of free movement? For instance, Member States with benefit in-kind or national health services are concerned about being forced to convert to reimbursement systems.
- Their competence to define the boundaries of their social protection system is being vigorously defended. In the *Smits* and *Peerbooms* cases, the power of the Member States to determine the material scope of application (the range of available treatment) raises many questions.
- One of the greatest concerns is no doubt that it would no longer be possible to exclude (private) providers from the system of social protection. In countries where, within the context of social protection, care is provided by a limited group of contracted providers, private providers have expressed particular interest in the *Kohll* and *Decker* judgements. They might refer to the decisions of the ECJ to claim reimbursement for their services provided to patients who are covered under the social health care protection system.
- Nearly all Member States are concerned about the impact of the rulings on cost containment policies and on reducing the supply of care and medical products. In general, they fear that these measures would be bypassed by using foreign services. Imposing relatively strict constraints on a medical profession might, especially in border areas, lead to patients or providers moving to the neighbouring country. Health care officials find it difficult to control foreign care providers concerning their compliance with measures ensuring cost containment and quality of care. What is more, national providers might consider the national regulations which are imposed upon them as distortions in comparison with foreign competitors.
- As for the waiting lists that exist in several Member States, they are the subject of a heated debate. Bypassing these waiting lists by using private care from abroad, which is subsequently reimbursed by the social protection system, would undermine this rationing policy and make it inoperative, or

[41] The report by an interministerial working group distinguished, on the one hand, the incidence of services provided within a market context (free access to the supplier) and on the other hand the system of providers contracted by the public health service.

even unfair with regard to patients who do not have sufficient means or knowledge to go abroad for treatment.

Taking all these possible factors into account, opening up the borders for health care could actually have a high financial impact. Hence, it is not the individual lawsuit between a patient and his own social protection institution that would undermine the financial equilibrium of the system, but the wider repercussions that it would cause internally. For these reasons, Member States generally seek to define free movement, in terms of access to health care, within a framework that enables them to maintain control over resource allocation and to ensure quality of care within their health protection system, without jeopardising the financial balance of their system.

1.8. Key issues in the political debate

The prospect of unconditional patient mobility, based on personal choice, is generally rejected. In practice this would correspond to "*à la carte*" affiliation to every social protection system and it would eliminate the checks and balances put in place by States on the organisation, functioning and financing of their systems.
The new procedure created by the *Kohll* and *Decker* judgements is not usually perceived as social progress. In fact, reimbursement on the basis of national tariffs does not seem to be very attractive to patients coming from Member States with low GDP. What is more, the obligation to pay the charges up front could certainly dissuade people on low incomes from using this solution. Hence, the free movement of patients seems to be aimed at the best-informed European citizens who have the required resources.

Some people, however, refer to the dynamism and the positive effects that could result from the jurisprudence as hitherto excessively strict national barriers are lifted. By seeking to promote the public interest in the area of health, cross-border co-operation, along with complementarity in the supply of health care, could improve the efficiency of health care systems and broaden the scope of treatment covered. Some people do recognise that the margins defined by social security co-ordination regulations are proving to be too restrictive. Generally, Article 22(1)(c) of Regulation 1408/71 has locked access to cross-border care rather than controlling it. The viability of the co-ordination tool will very much depend on its ability to adapt to socio-economic developments and the jurisprudence of the ECJ. In the absence of a Community social security system, however, it is the principal mechanism by which to guarantee social security rights across the European Union.

Some parties feel that the various governments have prevented an in-depth discussion and the establishment of a common position by relying upon the defensive argument that "*my system is different*". There is a risk of a split between those Member States ensuring access to care for their citizens through a system of reimbursement and those organising the provision of benefits in-kind either through a network of contracted providers or through a national health service[42]. It is therefore suggested that these issues should be studied from a broader perspective, while respecting the competence of the States to organise their own system. This would involve looking at the influence of various aspects of the market on the health care sector and the relationship between the institutions (financiers) and the market players (providers, suppliers). There is no stipulation in the Treaty that establishes specific targets in the area of social protection. The aim is therefore not to move the health care sector entirely beyond the scope of the Community rules on the internal market. It would no doubt be helpful to define the specific characteristics of the sector that ought to be preserved in order to guarantee a high level of social protection and health, and then find a fair balance between social and economic principles.

[42] The care networks developed within the framework of *"Health Maintenance Organisations"* (HMOs) in the United States limit access to care for its insured to contracted providers. This has not given rise to any objection from the *"anti-trust"* authorities that are responsible for ensuring compliance with freedom of trade. There are, however, criticisms at the policy level with regard to the American HMOs. These relate to the unfair restrictions and the lack of transparency with regard to the refusal of certain types of treatment.

Meanwhile, at a grass-roots level, some actors in the field of health care and social protection are turning towards a European strategy and looking for less bureaucratic solutions that are better adapted to their needs and those of their clients. At the hospital level, technological and scientific developments in medicine seem to be leading towards more concentration and specialisation as well as the creation of supra-national centres of excellence. As for those financing and insuring bodies, which have a certain autonomy in the management of their budgets, the possibility of signing contracts with foreign providers seems to be quite realistic and even feasible in the short term. This prospect is not necessarily limited to border areas. In Germany, for example, some of the major health insurance funds which are organised at company level (Betriebskrankenkassen)[43], are currently looking at the possibility of extending German statutory cover for their affiliated members to include treatment given in other Member States where offices of those major companies are based. This same approach, involving direct contracting with foreign providers, could also be used in tourist areas and in the centres of excellence referred to above.

PART 2: ANALYSIS AND POTENTIAL DEVELOPMENTS

Several factors could play a decisive role as regards scenarios and evolutions relating to the future European dimension of health care and social protection systems:

- case law developed by the Court of Justice on the basis of new cases referred to it;
- the ability of the Member States to develop health and social protection policies suited to people's needs and compatible with further European integration;
- pressure from citizens and to an even greater extent from other active grassroots actors for the creation of an internal health care market;
- the political will at Community level to take in hand a policy aimed at constructing a social Europe, in particular in the field of social protection.

Starting from a confused situation created by different interpretations of the judgements in *Kohll* and *Decker*, a number of objectives (whether or not progressive) of varying ambition could be pursued:

(1) clarifying the scope of the method of access to cross-border care established by the *Kohll* and *Decker* judgements, with a view to removing legal and administrative uncertainty;
(2) adjusting the various procedures governing coverage of cross-border care within the EU;
(3) developing a proactive policy on access to cross-border care for the purpose of making the procedures more flexible;
(4) defining the guarantees required to implement the internal health market with a view to ensuring a high level of social and health protection.

2.1. The aftermath *Kohll* and *Decker*: confusion and uncertainty

2.1.1. Unresolved questions

As the ECJ dealt only with the particular situations referred to it, many questions have remained unanswered following the rulings handed down in the *Kohll* and *Decker* cases.

- To what medical services and products does the principle of freedom of movement apply?

[43] These are health insurance funds administering statutory health insurance. They are established in companies employing at least 1000 people who are subject to compulsory health insurance. They are managed jointly by the employer and the workers. Among the largest are: Siemens and Volkswagen. Some of them have come together to form a discussion group ("*Nassauer Kreis*") to look at innovations at the European level.

- What methods of organising access to treatment are excluded from application of the principles governing freedom of movement for goods and services?
- To what extent could application of the principles governing the internal market weaken or even neutralise cost containment measures?
- What powers do Member States retain as regards making access to treatment subject to certain conditions (e.g. age) or procedures (waiting periods) and, more generally, what powers do they have to define the personal scope and material scope as well as the scope of implementation (e.g. range of authorised providers) of their health care protection systems?
- Under what conditions can restrictions of free trade by prior authorisation be justified by well-founded exceptions based on public health or the overriding reason of the general good?
- In what way can prior authorisation under Article 22(1)(c) of Regulation 1408/71 be considered to be a justified hindrance of the principles of free movement of goods and services?
- Should prior authorisation be classified as direct discrimination or as a non-discriminatory measure and can the financial arguments based on the overriding reason of the general good therefore be relied on to justify this restriction of the free trade?
- How at one and the same time can alternative methods of social protection based either on the co-ordination policy (E111, E112) or on the principle of free movement of goods and services coexist?
- How to apply equivalence between services belonging to different health care systems where they are integrated and financed according to different rules?
- How to check the genuineness of services and how to ensure the quality of treatment reimbursed under the procedure established by the judgements?
- Does the principle of freedom of movement also apply to private health insurance?
- May third-country nationals benefit from the principle enunciated in the rulings?
- etc.

All these questions have given rise to confusion and uncertainty.

2.1.2. Administrative and legal confusion

Firstly, the judgements in *Kohll* and *Decker* mark a break in the homogeneity of views and the conception regarding access to treatment abroad which has prevailed to date in the European Union and more widely among the EEA countries. Some Member States have now incorporated the new procedure established by the ECJ on the basis of the Treaty into their legislation. Others continue to rely only on Regulations 1408/71 and 574/72. This situation could give rise to inconsistent practices and unequal treatment not only among Member States but also among citizens within a particular country.

In addition, the coexistence of different procedures within a given country will inevitably increase the administrative burden as regards coverage of treatment received abroad. Moreover, the so-called *Kohll* and *Decker* procedure is proving to be more time-consuming than the one established under the current rules. The need to reimburse the cost of medical services and products obtained abroad on the basis of the 'home country tariffs' makes it necessary for Member States to check on the services provided abroad, identify them in accordance with their proper nomenclature and fix the tariffs for them on the basis of the applicable rules. However, in many situations this practice of fixing tariffs and conducting checks is proving to be very difficult if not impossible [44].

The problems encountered at administrative level could entail legal uncertainty for patients. If a person insured under a social security scheme is unable to provide proof that payment has been made,

[44] In addition, application at national level of limitation or exemption mechanisms relating to patients' co-payments beyond a certain ceiling further complicates the question of validation of reimbursement of the cost of the services obtained in another Member State. That being said, other Member States which, in the context of their health care system, do not apply fee for service are faced with the problem that they have no basis for reimbursement.

if the national conditions governing reimbursement are not fulfilled or if the service does not fall under the nomenclature of services covered, reimbursement may be refused. In addition, patients will no longer have the guarantees which they enjoy in the context of the E112 procedure. In each instance of treatment the patient will be obliged to make an advance payment on the costs involved, and the reimbursement rate will not be related to the actual expenditure incurred.[45]

2.2. Clarifying the scope of *Kohll and Decker*

2.2.1. The legal spectrum

In this context, the first priority is to provide administrative clarification, restore a unified concept among Member States regarding reimbursement of the cost of treatment received abroad and remove the legal uncertainty created by the rulings.

The ECJ could be the first actor to make an early contribution to the objective of clarification by replying to the requests submitted to it for preliminary rulings. In these pending cases, the ECJ should be able to specify, in the first place, the conditions to be fulfilled by persons insured under a social security scheme in order to obtain reimbursement of the cost of the medical services provided in another Member States in accordance with the principles specified in the judgements in *Kohll* and *Decker*.

With a view to demarcating the extent of this new procedure established by the ECJ, several elements can be taken into account. A particular aim should be the provision of a balanced answer applicable to all types of health care protection systems and not simply confined to reimbursement mechanisms:

- The first question to be resolved is whether medical goods and services in fact fall within the scope of the free movement of goods and services within the meaning of the Treaty.
- If so, the impact of these principles on the measures taken by the Member States when organising social protection systems should be assessed.
    - Firstly, it should be determined whether the measures in question constitute a barrier to the freedom of movement.
    - If this is so, it will then be necessary to examine whether the barriers can be justified on the basis of the exemptions provided for in the Treaty or those created under Community case law[46].
    - Finally, it is necessary to evaluate whether the justifiable measures are necessary and proportionate.

On the basis of this evaluation framework, several scenarios are conceivable.

(a) Medical treatment is excluded from the principle of freedom to provide services on the grounds that it is not of a remunerative nature.[47] In such a case, the condition relating to prior authorisation can be maintained. This argument could be applied to all services falling within the scope of social

[45] In this sense, the enthusiastic and rather unbalanced information disseminated in the press in some Member State following the rulings, has created erroneous expectations among patients. It is therefore essential that access to health care abroad should be accompanied by correct and precise information. It is difficult to speak of free choice if the patient does not have a clear and prior view as regards the treatment available, its cost, and the level of coverage under the applicable social security system.

[46] See *Cassis de Dijon* Case C120/78 (1979) ECR 649

[47] In its ruling in *Humbel*, the ECJ used three criteria to place public education outside the scope of freedom of movement for services: (1) a price is not fixed between the service provider and the recipient; (2) the service is supplied by a State body; (3) the service is financed mainly by the State budget. As the ECJ indicated, the fact that the recipient must contribute in part to the cost of the system does not call into question the nature of the activity. Even if pupils have to make a small contribution to the cost of education, in particular by paying schooling costs, public education does not thereby become a service within the meaning of the Treaty.

protection[48]. On the other hand, it could be limited to services in respect of which patients do not incur any expenditure (systems involving benefits in kind or third party payer[49]). This was the context for the Opinions of the Advocates General in the *Vanbraekel* and *Smits/Peerbooms* cases.[50]

(b) A medical service is subject to application of the principle of free movement of goods and services. However, prior authorisation is not considered to be a barrier to this principle as it does not discriminate against foreign providers.
Traditionally, the ECJ has given a very broad interpretation to the concept of restriction of intra-Community commerce[51]. A few years ago it revised its thinking: if a measure affects the volume of goods sold or services provided, it will not restrict commerce where it involves "*selling arrangements*" which affect only the total volume of goods and services supplied and which do not entail discrimination in fact or in law against goods and services originating in other Member States[52]. Member States would therefore not be under an obligation to justify such measures.

(c) Prior authorisation is a barrier to freedom of movement for medical goods and services, although it can be justified. As far as concerns social health care protection, the ruling in *Duphar* laid down the essential basis for derogation: Member States are authorised to make coverage of medical services and goods subject to conditions such as prior authorisation provided that the criteria used are objective and non-discriminatory as regards services originating in another Member State[53].

(d) Prior authorisation is a barrier to freedom of movement for medical goods and services which cannot be justified or which is not necessary or proportionate in relation to the underlying objective. In such a case, the prior authorisation may not be maintained, and the reimbursement procedure in accordance with the principles laid down in the *Kohll* and *Decker* judgements applies.

To situate the *Kohll* and *Decker* cases into these various scenarios it is important to analyse them by taking into account features other than the granting of outpatient benefits in the form of reimbursement by the Luxembourg health insurance funds.

- the German orthodontist, irrespective of his status as a contracted or private provider under the German statutory health insurance system, was not bound by any agreement with the Luxembourg health insurance system. Therefore, in relation to the Luxembourg patient, Ms *Kohll* - who did not apply for the Community social security co-ordination procedures (E111 or E 112) - he was free to fix his fees in the same way as for a private patient.
- In Luxembourg, all doctors (general practitioners and specialists) are compulsory contracted with the statutory health insurance. Consequently, all doctors established on the Luxembourg territory,

[48] Even though this would appear to go against the decision in the *Kohll* case.
[49] However, in his Opinion in *Humbel*, the Advocate General stated that the manner in which the State finances a public service is not decisive: "*…remuneration is not provided, to my mind, when the recipient receives the service without charge or he pays for it with a grant already received by the State and then all or a portion of that charge is reimbursed by or on behalf of the State...*"
[50] This argument cannot be applied to medical products. The ECJ has stated that the principle of freedom of movement applies to any product crossing a national border for the purpose of a commercial transaction.
[51] ECJ, 11 July 1974 in *Dassonville*, C-8/74: any State measure which makes it more difficult to supply a good or service originating in another Member State restricts intra-Community commerce. The smallest barrier to freedom of movement, whether direct or indirect, real or potential, is sufficient to the infringe the principle of freedom of movement even if it is non-discriminatory in relation to national service providers and those in other Member States.
[52] ECJ, *Keck* and *Mithouard*, C-2670268/91, ECR 1993, I-6097. Likewise demarcation of the social protection system by Member States could be considered to be "*selling arrangements*" or rather "*distribution arrangements*".
[53] ECJ, 7 February 1984, *Duphar*, C-238/82.

are automatically included into the contractual system and must therefore respect the conventional tariffs fixed under the nomenclatures for doctors and dentists[54].

The procurement mechanism of the health care protection system therefore appears to be a factor of key importance for interpreting the rulings. The manner of purchasing health care and contracting with the medical providers and suppliers forms an integral part of Member States' competence to organise their social security schemes[55]. The ECJ confirmed this in its ruling in *Sodemaré*[56] From this ECJ case law it can be inferred that the free movement principles do not preclude a Member State from demarcating the sphere of providers and suppliers in the context of its social protection system. However, it may not discriminate against them on the basis of nationality or place of establishment.

2.2.2. The role of policymakers

The ECJ is not a policymaker, it is a guardian of the interpretation and uniform and proper application of Community law. It is therefore limited as regards what action it can take[57], especially as the diversity and complexity of the health care sector and social security coverage require implementation of a policy which is clear and easily applicable to other situations. However, applying an ECJ decision in an individual case to other services, sectors, health care systems and countries is a very difficult matter and can be open to question.

It is therefore essential that the reflection which has been conducted by the ECJ and which is inevitably of a fragmentary nature, should be accompanied or extended by action on the part of other actors with a view to restoring, in the short term, the legal certainty necessary for the citizens of the EU, their authorities and their providers.

- Firstly, each Member State could clarify the situation for its socially insured persons by seeking to make its social protection and health care systems "Euro-compatible"[58]. In this way, they would limit the risk of disputes.

  As Member States are free to organise their social protection systems relating to health care in accordance with their own priorities and standards, the three essential elements that determine the boundaries of social health care are defined differently from one Member State to another:

  a) the categories of persons covered (the personal scope);
  b) the goods and services covered (material scope)[59];
  c) the terms of entitlement, e.g. the groups of authorised providers and suppliers under the social health care protection system (scope of implementation)[60].

[54] It can be noted that the rulings in *Kohll* and *Decker* have given rise to strong opposition among the Luxembourg medical profession as they feel themselves to be disadvantaged in relation to foreign colleagues who, following the judgements, also benefited unconditionally from reimbursement of the cost of the services provided without having to comply with the contractual tariffs or any other negotiated commitment.

[55] In general, a distinction can be drawn between **inclusive systems** which include all providers established on the territory within the scope of the health insurance scheme on the one hand and **exclusive systems** on the other which limit social security coverage to a restricted group of providers who have concluded an agreement with the social security authorities.

[56] ECJ, 17 June 1997 in *Sodemare*, C-70/95. The ECJ ruled that a Member State may in fact consider that , for the purpose of achieving the social objectives of its social assistance system, the scope of the agreements with the social security authorities has to be limited to private operators working on a non-profit basis.

[57] It is for the national judicial authorities in the first instance to decide on the questions to be submitted to the ECJ. The ECJ is not empowered to examine the facts of a case or the reasons for the questions. The ECJ does not give advisory on general or hypothetical questions. The questions referred to it must relate to a dispute.

[58] The question of compatibility of health care systems with the Community competition rules is not dealt with in the context of this report.

[59] The competence of Member States to define the care package covered by the social protection system in accordance with their choices and priorities was indirectly contested in the *Smits* and *Peerbooms* cases.

The ECJ confirmed in *Kohll* and *Decker* that the Member States have the discretion to organise their own social security systems but this discretion must be exercised according to the confines of the EC rules on free trade. As far as these rules apply to medical services and goods, this would require that the criteria established by the social protection systems should not directly or indirectly discriminate against providers or suppliers established in another Member State without legitimate cause (derogation from the freedom of movement). Application of this non-discrimination principle in the context of cross-border treatment could mean that:

- a health care provider may not be prevented from joining the contractual system of another Member State on the sole grounds of nationality or place of establishment, but only on the basis of legitimate, objective and proportional criteria[61];
- where a social protection system also reimburses services provided by non-contracted practitioners established on its territory, it may not exclude those of (non-contracted) providers in another Member State[62].

- On a Community level, the best way to clarify the case law of the ECJ for the purpose of applying it to other systems - apart from adaptation of the legislative framework (the Treaty, Regulations 1408/71 and 574/72), an aspect which will be developed in the following point (*see 2.3.2*) - would be to prepare an interpretative communication. In this communication, the Commission could explain the ECJ judgements and emphasise their consequences for both the Member States and patients. Even if this type of instrument is not of a binding nature, the ECJ has already agreed to refer to it for the purpose of interpreting national and Community provisions[63]. To make this instrument even more authoritative, the Council could adopt it[64].

2.3. Adjusting access procedures to cover cross-border care

2.3.1. The dual system and entanglement of procedures

In situations in which the reasoning put forward in the judgements in *Kohll* and *Decker* is applicable, a patient who wishes to receive treatment in another Member State now has two options as regards obtaining social security coverage. This is due to the fact that the ECJ has left explicitly intact Article 22(1)(c) of Regulation 1408/71. Thus, a patient may:

- either obtain prior authorisation from his or her social security institution and then obtain coverage on the basis of the tariffs of the country in which the service has been provided (E 112 procedure); or
- go directly to another Member State to receive the treatment (with immediate payment for the service) and on return home obtain reimbursement from his or her health insurance fund on the basis of the tariffs applied in his/her home state (*Kohll* and *Decker* procedure).

These two procedures are clearly different. The first one, which is governed by the social security co-ordination system, integrates a patient into the social protection scheme of the State where he/she

[60] If a patient steps outside these boudaries, for example by consulting a private (non-contracted) practitioner or by obtaining services not covered by the patient's scheme, the patient ceases to be eligible for social protection and becomes a private patient. Such a patient is therefore not eligible for coverage either in the patient's country or outside it.

[61] It can also be noted in this context that in its judgement in the *Tögel* case (ECJ, 24 September 1998, C-76/97), the ECJ clearly indicated that agreements concluded with service providers or suppliers of goods in the social security context should comply with the rules governing public procurement.

[62] For example, the Belgian health insurance scheme reimburses the cost of services provided by Belgian doctors who have not concluded an agreement with the social security authorities.

[63] ECJ, *Grimaldi*, C-322/88, ECR, 1998 4407: This case involved a recommendation.

[64] Another option would be to annex a protocol to the Treaty at the forthcoming Intergovernmental Conference. This method was used previously in a similar situation in order to clear up the uncertainty created by the judgement in *Barber* (ECJ, *Barber*, 262/88, ECR 1990 I-1889) regarding Article 141 (former article 119) of the Treaty. This is Protocol 117 which was annexed to the Treat of Maastricht in 1992. A *Kohll* and *Decker* Protocol could precisely demarcate the scope of the rulings. As it would be in the Treaty it would be binding on the ECJ.

receives treatment. Thus the patient is treated "*as if he or she were insured with it*". A patient who benefits from the second procedure is not integrated in any way into the social protection system of the country of stay, as he/she seeks only the service of a provider established there[65]. On return to his or her country of residence, the patient will claim reimbursement from his or her social protection system "*as if he/she had obtained the medical service or good at home*".

On the other hand, patients using the various procedures for access to treatment abroad are not easily identifiable, as they only differ as to the reasons or motivation for recourse to treatment abroad. Thus, the procedures could overlap as follows:

- E111 (emergency care) and E112 (planned care): in view of the restrictions on the granting of prior authorisation some patients will try to obtain reimbursement of the cost of the services received by feigning an emergency case during a stay in the country where the service was provided.
- E 112 and *Kohll*/*Decker* (private care[66]): if authorisation is refused or if the tariffs of the country of residence are more attractive, the *Kohll* and *Decker* procedure would be an alternative.
- E 111 and *Kohll*/*Decker*: if it has not been possible to settle the formalities involved in the E111 procedure, the patient may in certain cases receive reimbursement in accordance with the tariffs of his or her State of insurance.

This blurring of possible procedures could give rise to legal and administrative problems, especially if patients were speculating in order to obtain the treatment they want at the lowest cost.

2.3.2. The need to rank procedures

Two options are conceivable for the purpose of ending the confusion created by the coexistence of different procedures:

- **Abolish either procedure**[67]

  Even if the ECJ has explicitly maintained the prior authorisation procedure (E112 procedure) provided for in Article 21(1)(c) of Regulation 1408/71[68], it is not excluded that the Community legislator could amend it for the purpose of terminating the procedural dualism involved. The best way to do this would be to adapt this provision of European secondary legislation to the principles underlying the procedure based on the judgements in the *Kohll* and *Decker* cases. This would mean:
  - abolishing the condition of prior authorisation in Article 22(1)(c);
  - adapting the relevant legislation (at least as regards the applicable tariffs) to that of the State of affiliation.

- **Rank the various procedures or establish a hierarchy among them**

  In the event that the dual system is to continue, some have proposed that it should be co-ordinated in fact or in law in order to make the two procedures complementary or subsidiary to each other and not antagonistic or competitive.

[65] It would not matter if this provider had concluded an agreement with the social protection system of his country.
[66] In this context, private treatment is understood to mean a service performed by a provider who is not contracted by the social protection system of which the patient is a member and which reimburses the cost of his treatment..
[67] As the new procedure established by the rulings in *Kohll* and *Decker* is inferred from application of the principles governing the freedom of movement contained in the Treaty and as it is not laid down in a Community legal instrument, the only way to abolish this procedure would be to deny, in the Treaty itself, application of the basic principles to social protection.
[68] Although the Luxembourg provision declared to be invalid by the ECJ was the same as Article 22(1)(c) of Regulation 1408/71, the ECJ has defended retaining this Article by emphasising its objective, in particular that of enabling the insured person to receive treatment in another Member State "in the event that the transfer becomes necessary in view of the state of health of the person concerned and provided there is no additional cost".

There would not appear to be any justification for specifying the primacy of either in relation to the other on the basis of a hierarchy of norms[69]. Establishing a hierarchy would therefore require active intervention by the policymakers.

Theoretically, the integration of the *Kohll* and *Decker* procedure as a subordinate procedure into the framework of Regulations 1408/71 and 574/72 would be feasible as Article 34 (4) and (5) of Regulation 574/72 already provides for a posteriori reimbursement in accordance with the 'home State' tariffs when it has not been possible to comply with the formalities relating to the E111 procedure (*see footnote no 17*).

The *Kohll* and *Decker* procedure could be demarcated on the basis of various criteria.

- The socially insured person could be obliged to opt for either procedure at the time of treatment (in order to avoid speculation). Use of an E111 or E112 form would therefore rule out any use of the *Kohll* and *Decker* procedure.
- The *Kohll* and *Decker* procedure could be limited to those services that do not fall within the ambit of Article 22 of Regulation 1408/71, in particular non-urgent and unauthorised treatment, treatment provided by private providers (whose services are not covered by the country of service) or services not covered by the social protection system of the State in which the treatment has been provided.
- reimbursement according to the *Kohll* and *Decker* procedure could be limited to certain types of services and/or services whose cost does not exceed a specified amount.

In the absence of intervention by the Community legislator, Member States could individually adopt provisions with a view to establishing a hierarchy for the procedures[70]. In the event that these measures were disputed, the Member States could argue that an effective and equitable social security system requires this kind of hierarchy.

However, the unanimous agreement of all Member States is required if the *Kohll* and *Decker* principles are to be integrated into the Regulations, either as a main and single procedure or as a subordinate procedure. Independently of the consent of the Member states, the effect of this working hypothesis[71] would not be to eliminate the procedure based on the Treaty. Indeed, the ECJ could in future always amend or extend the law deriving from freedom of movement for goods is services by relying directly on the Treaty, thus creating a third procedure.

2.4. Developping a proactive and more flexible policy of cross-border care

Independently of the questions specifically related to the scope of the *Kohll* and *Decker* ruling and its interaction with European social security co-ordination, Member States might as well develop a voluntary policy concerning cross-border access to care. This proactive policy could in fact be conducted within the framework of the existing E112 procedure. It would aim at a better meeting of people's needs and expectations as well as keeping pace with current and future developments in the field of medical practice.

2.4.1. The border areas

During the last decade, initiatives and pilot projects have been developed to improve access to cross-border care in certain border areas essentially for the benefit of local residents. Experiments of this type seek to promote complementarity for existing medical services on either side of the border, in

[69] The principle of the primacy of the Treaty (primary law) over a Regulation (secondary law) only applies in cases where there is a conflict and not, as in this case, where a citizen is free to choose from two equally valid legal options.
[70] Luxembourg and Belgium have established a specific procedure for outpatient treatment (see 1.8.) for the purpose of applying the ECJ case law. However, these two Member States give priority to the E112 procedure.
[71] In fact very few respondents in the survey carried out are in favour of such a scenario.

particular through the conclusion of bilateral agreements. They relate particularly to specialised medical practices such as cardiology, traumatology, emergency treatment, paediatrics, neonatology, dialysis and radiotherapy. All these "Euro-regional" projects emphasise the need to involve all health care actors (both insurance bodies and providers) and to improve the level of information for local residents in this matter.

Given the margin of discretion left to the Member States by the social security co-ordination mechanism as to authorisation and financial settlement of cross-border care, these actions in border areas are actually developed within this legal framework.

Policy action in this field is built around three levels:

- The **microlevel**: at which action aims at solving local problems of insufficient treatment provision on one side of the border on the basis of complementary services on the other side. The instruments used are exchange and co-operation between specific health care institutions and reciprocal agreements.
- The **mesolevel**: at which action aims at a cross-border reorganisation of resources used in border areas in order to improve the state of health of the people living on these territories. Bilateral agreements (approved by the national health care protection bodies) as well as other instruments (e.g. a border health observatory) or measures (e.g. common standards for regulation of medical practices on either side of the border) could enable joint planning for border infrastructure and/or facilitate access to cross-border care for the inhabitants of border regions (e.g. automatic access to care on either side of the border, compatibility procedures relating to data transmission, simplified financial rules etc.).
- The **macrolevel**: at which the objective would be to promote and assist projects designed to improve access to treatment and the effectiveness of health care systems in the border areas on a European level using recommendations and action programmes. This would imply co-ordination among the various current projects and their monitoring at the level of the competent European bodies such as the Administrative Commission of the European Communities on Social Security for Migrant Workers.[72]

In the context of the new Community strategy aimed at increased co-operation among Member States in the field of social protection[73], the Commission and Council could provide the impetus essential to initiating a specific approach in the border areas[74]:

- by drawing up instruments such as action programmes designed to promote access to cross-border treatment and improve the effectiveness of health care systems. This is all the more necessary because most of the various Community programmes in these fields (e.g. Interreg II, Biomed II) are now coming to an end. These instruments could become an engine for dynamic Euro-regional development in the fields of health care and patient mobility;
- by (support for) the creation of regional observatories relating to health care and access to treatment. These observatories would be a preferred place for studies and for developing and evaluating various kinds of complementarity and synergies for inter-regional and cross-border health care provision;
- by preparing a recommendation regarding support for implementation of a policy and instruments with a view to achieving the above objectives.

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[72] It can be noted that the Committee of the Regions has recommended to the European institutions that they promote co-operation with the local and regional authorities, in particular in border areas on the basis of practical initiatives and development projects for the purpose of remedying specific problems in the field of health. (Opinion of the Committee of the Regions on the role of local and regional authorities in the reform of the public health care systems in Europe, 13 April 2000, Committee of the Regions 416/99 final).

[73] See Communication of the European Commission entitled *A concerted strategy for modernising social protection* (COM (1999) 347 final of 14 July 1999); Council Conclusions of 17 December 1999 on strengthening co-operation with a view to modernising and improving social protection, OJ C 8, 12 January 2000, pp.7-8.

[74] However, a policy action cannot be made general or imposed on all border areas. Each region has to be evaluated in accordance with its particular geographical, economic, demographic and infrastructure capacity features (e.g. an excess or shortage of facilities, overabundance of medical services etc.).

2.4.2. Centres of excellence

Technological and scientific developments in the field of health care lead towards concentration of medical know-how, financial resources and facilities. This is not only necessary for reasons of containing costs and achieving economies of scale, it is to an even greater extent inspired by the need to maintain or improve the quality of care. The practice of high-risk, complex and delicate medical interventions now goes beyond regional and national territorial areas as these have become too small. What we are now witnessing is the emergence of large-scale hospital centres of excellence which are determined to attract patients and which go beyond the geographical confines traditionally applied to hospitals.

This new situation cannot be ignored by policymakers involved in the future of health care provision and protection. To what extent does the restricted access to health care abroad, still meet the demands of patients in need of specialised medical treatment?[75] Would it therefore not be appropriate to design palliative or corrective options for these people? As a corollary, should Member States not reflect on the inherent mission of their medical infrastructure, equipped with all the technical and human resources required for specialised medical treatment, to receive these patients from other Member States?

This necessary complementarity between people seeking treatment and facilities capable of treating them is an important part of the European integration process, in particular for achieving the express EC goal of a minimum level of social cohesion.

Under this approach, an initiative could be taken at Community level to explore and study, inter alia, the operational framework needed for:

- an inventory of Member States' needs in terms of pathologies to be treated;
- an inventory relating to services of excellence and their capacity;
- an analysis of existing and potential types of partnership (definition of the administrative and financial settlement for regulating cross-border patient flows);
- an analysis of contractual instruments (bilateral and multilateral agreements, direct contracting with health care facilities) and instruments for setting tariffs and prices (appropriateness, feasibility and procedures relating to fixing tariffs at European level);
- an analysis of existing and possible types of (clinical) prioritisation that ensure a balance between equal treatment of patients and the performance of national public tasks;
- research into possible techniques relating to solidarity and to risk sharing among Member States in the funding of this European network of excellence (appropriateness, feasibility, procedures);
- a definition of common quality standards.

2.4.3. Upgrading the co-ordination instrument of social security systems

The basic question here is to what extent Regulations 1408/71 and 574/72 are capable of encouraging and facilitating a proactive policy in the field of cross-border care.

[75] Some Member States have already had to tackle this basic question. These are mainly countries with a small population whose health care systems do not have sufficient or adequate infrastructure. The Grand Duchy of Luxembourg is the most relevant example for the purpose of conducting a forward-looking reflection and drawing up a hypothetical approach relating to specific and well-founded activities.

2.4.3.1. Its use by the Member States

Article 22 of EC Regulation 1408/71 allows Member States to implement a restrictive authorisation policy, but it in no way obliges them to do so[76]. The *Pierik* rulings (*see 1.2.2.*), placed the patient's state of health as the decisive criterion for granting an E112 form. As a reaction, the Member States took unanimous action to modify Article (22)(2)(2), which defines the situations in which Member States are obliged to give authorisation. The new version gives them greater power to refuse.

The *Kohll* and *Decker* rulings and their wide response in public opinion could actually be an incitement for Member States to ease their authorisation criteria. In any case, faced with the sometimes alarming problem of waiting lists, Article 22(2)(2) does, all the same, appear to offer patients some guarantees against rationing policies if these are seriously prejudicial to the patients' health and their basic rights of access in the State of residence.

2.4.3.2. Its adaptation with a view to a more flexible authorisation policy

In order to facilitate the development of a policy of access to cross-border care, EC Regulation 1408/71 could be modified in order to:

- widen the field of authorisation for care (E112) which cannot be refused (art. 22(2)(2)) to: outpatient care, specific pathologies, excessive waiting times, border areas, etc.
- improve the convergence and the coherence between Member States with regard to authorised cross-border care (for example, through a recommendation).
- introduce a wider definition of "*immediately necessary*" care (article 22 (1)(a)) within the framework of the E111 procedure, integrating chronic care, childbirth etc.
- widen the categories of persons for whom the condition of emergency is lifted (art. 22(2)(1), art. 31);
- extend the rights of frontier workers, who currently enjoy dual access to care on either side of the border, to all persons residing in a border area[77].

In order to modernise social security co-ordination with regard to health care and in order for it to integrate the needs and the changes currently under development, various initiatives are necessary to ensure:

- better awareness and understanding of the instrument by users;
- better statistical information about cross-border care (volume of authorisations granted and refused, types of care and pathologies dealt with, places where the care is delivered etc.)
- easy and rapid transmission of data between Member States, health insurance and health care institutions, by means of computerised supports or the development of telematic networks accessed by magnetic or smart cards[78];

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[76] In his conclusions relating to the *Smits* and *Peerbooms* cases, the Spanish Advocate General deplores the fact "*that the competent institutions of Member States apply this rule in such a restrictive way and that they grant so few authorisations each year whereas, under their control, this could be a very valuable instrument for reducing long waiting lists which patients come up against in certain Member States*." (consideration 79);

[77] Recently, the European Commission proposed a reform and a simplification of regulation 1408/71. Apart from a reformulation (more positive) of article 22(2)(2) these proposals contain no changes with regard to current procedures. However, an extension of entitlements are proposed for certain categories (students, unemployed looking for work, retired frontier workers and their family members), (EUROPEAN COMMISSION, Draft regulation (EC) of the Council dealing with the co-ordination of social security systems, COM (1998) 779 final, O.J., C 38/10, 12.2.1999);

[78] The TESS program has for a number of years been attempting to computerise exchanges of information based upon the E-forms. For healthcare, the Build 5 project is exploring the transmission of data relating to the financial settlement between some Member States (B, D, DK, F, GR, I, NL). After becoming operational (end of the year 2000), the computerisation of the forms granting access to the right will be dealt with. In addition, a number of pilot projects, such as Transcards (B-F) and Netlink (F-I) are already experimenting with the use of remote network technology and cards in the administration of cross-border flows of patients.

- a reduction of the existing (tedious) administrative burden by the simplification of procedures and the general implementation of flat rate financial settlement for the least expensive services.

If the *Kohll* and *Decker* judgements are to be unanimously applauded for one thing, it was because they filled a social vacuum for nationals of third States who are still excluded from the co-ordination of their social security rights on the basis of their nationality (even though they contribute to the financing of the health system in the Member State in which they reside[79]). The extension of the personal scope of application of regulation 1408/71 to all persons covered by social protection systems would constitute not just a step forward in social terms, but also an administrative simplification[80].

2.5. The implementation of the internal health market: necessary guarantees

2.5.1. The obligation to ensure a high level of social and health protection

More and more voices are now being heard saying that health is not an economic product but a social good for which specific ethical standards should be taken into consideration. The implementation of the internal health care market risks damaging this specificity, even though it may produce beneficial effects in terms of increased efficiency and productivity.
The Treaty recognises the specificity of several sectors such as agriculture, transport and the environment as they were faced with the application of internal market rules. It would then be difficult to explain why health and social protection should not be awarded such recognition, all the more so as the Treaty states that one of the objectives of the EU is to attain a high degree of social and health protection[81]. The new article 152(1) of the Treaty goes even further, since it imposes an obligation *"to ensure"* a high level of protection of human health in all EC policy matters.

In the *Kohll* and *Decker* judgements the ECJ rejected the argument of the Luxembourg government raising the need to monitor the quality of care given. According to the ECJ this could not justify prior authorisation for health care abroad on the basis of the public health derogation to the free movement of goods and services. It stated that the quality of healthcare is comparable throughout the whole of the EU, mainly since EC directives have implemented mutual recognition of diplomas in the medical professions. The ECJ was criticised on this point. Although these directives establish a minimum harmonisation of training programmes for a limited range of health care providers, these minimum standards are not capable of guaranteeing a comparable level of quality in all of the Member States. In fact, they are rather vague, containing no medical practice standards based upon accreditation norms and obligations for continuous training. Therefore, we must consider that the ECJ has taken up a position on principle rather than having passed a well-founded judgement on this issue.

Today, the quality of care is becoming a central concern of care systems. National health policies are more increasingly imposing procedures in order to better regulate medical practice and access to certain categories of care. The planning of the medical infrastructure, the introduction of medical guidelines and the creation of accreditation procedures also aim at raising quality standards and serve public health interests [82].

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[79] NICKLESS J., *Kohll* and *Decker: a new hope for third-country nationals*, Eurohealth, vol. 5, n° 1, 20-22;
[80] The removal of the condition of nationality (European) is again taken up in this proposed reform (EUROPEAN COMMISSION, Draft regulation (EC) of the Council dealing with the co-ordination of social security systems, COM (1998) 779 final, O.J., C 38/10, 12.2.1999);
[81] In its *Albany International* ruling, the ECJ based itself directly on the objective of attaining a high level of employment and social protection, given in Article 2 of the Treaty, in order to counterbalance the community rules on competition (ECJ, 21 September 1999, *Albany International BV*, C-67/96);
[82] France has, for example, recently taken a series of measures to improve, or even to ensure, the quality of the care. A national Agency for accreditation and assessment on health matters is entrusted with appraising the quality of the health care establishments. Health care networks and health co-operation groups must encourage the structuring of health care provision. Compulsory guidelines of evidence-based medicine as well as compulsory continuous medical training of doctors must allow the updating of medical practices.

2.5.2. Establishing a European reference framework for social and health protection

In order to counterbalance the principles of the internal market, some deem it necessary to enshrine social protection and health as areas of general interest in the Treaty. Others believe that the complementary role of the EU on the basis of a correct interpretation of the subsidiarity principle should be recognised. This would imply that when Member States no longer seem to be in a position to react in an appropriate way, it is reasonable to envisage Community measures.

From the perspective of preserving a high level of social and health protection, initiatives could be taken to:

- clarify and give concrete expression to the notion of general good applied to the health and social protection sector[83].
- create a European reference framework - rather an incentive than normative one - in terms of quality standards, criteria for good medical practices, rules on equivalence of competence and medical practice, hospital accreditation, medical prescription, control, etc[84].

It is evident that the Commission could take the initiative to launch this ambitious approach.
Under the new strategy envisaging a reinforced co-operation between the Member States in the field of social protection, four key objectives have been set, one of which is that of "*guaranteeing a high and sustainable level of health protection*"[85]. This strategy should integrate access to healthcare, in general, and to cross-border care, in particular. On this issue the Committee on Employment and Social Affairs of the European Parliament is preparing an initiative aimed at guaranteeing access to health care, that also includes complementary health insurance[86], and to put into place instruments such as: the inscription of the principle in the Charter of Fundamental rights, the creation of an observatory on health and access to health care and the definition of a common notion of universal service.
In addition, the new Community strategy on public health could offer a solid basis for common reflection on a health reference framework[87]. With the enlargement of the European Union, the need for this instrument is becoming vital.
Finally, the putting into place of an overall system of information making it possible to proceed to a critical assessment of the various health systems[88], could become the point where actions relating to social protection and public health meet.

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[83] In its interpretative communication "*Freedom of providing of services and general good in the insurance sector*" (2000/C 43/03, O.J., C 43/5), clarifying the notion of general good in the insurance field, no reference to the health insurance sector has been made.

[84] Let us know that the medication sector, a process of several years is in progress in order to put into place certain guarantees. The secondary community law establishes the minimum norms for launch onto the market, creates a system of authorisation and imposes transparency in the fixing of prices. The explicit objectives of this legislation are the protection of public health and the creation of the internal market.

[85] Communication from the European Commission "*A concerted strategy in order to modernise social protection* (COM (1999) 347 final dated 14th July 1999). Council Conclusions of 17 December 1999 on strengthening co-operation with a view to modernising and improving social protection, OJ C 8, 12 January 2000, pp.7-8.
The Commission proposes improving the efficiency of health systems, guaranteeing access for all to high quality services and reducing inequalities with regard to care, further sustaining long-term care for fragile elderly people and prioritising the prevention of illness and the protection of health.

[86] EUROPEAN PARLIAMENT, COMMITTEE ON EMPLOYMENT AND SOCIAL AFFAIRS, Working document on complementary health insurance, PE 286.183, 16th March 2000.

[87] Communication from the European Commission on the European Community health strategy, *Proposal of a programme of action of community action in the field of public health* (2001-2006), COM (2000) 285 of 16th May 2000.

[88] See press release (IP/00/484 of 16th May 2000) "*The European Commission launches new proposals for analysing and combating illness in Europe*"

2.5.3. The constitution of a European forum on health policy and access to care

The approach described above will only be fully effective if all actors in the field of health care and its social protection play an active role in putting it into action. Reactions to the *Kohll* and *Decker* rulings have clearly shown the need for a wide debate on the various aspects of health and access to intra-community care, integrating the various players involved (social security institutions, mutual health funds, health professionals, health care establishments, organisations representing patients and medical consumers, etc.) This is why the creation of a European forum could be envisaged as a way of dealing with these problems[89]. This forum could at the same time be:

- the place where access to care, in general, and to cross-border care, in particular, is listed, analysed, debated, assessed at Community, national or (inter)regional level.
- the centre for prospective studies on the supply of health care in a context of its restructuring with regard to border areas, development of centres of excellence, etc.
- the centre of a process of collecting and defining trans-national medical practices with a view to drawing up a classification of acts (thesaurus) as a tool for information and exchange.
- the place where initiatives and actions taken throughout the EU are exchanged in order to build comparable quality standards, norms for medical equivalence, criteria for mutual recognition of practices (for approval, for monitoring, etc.) are exchanged.

[89] Let us note that the Economic and Monetary Commission of the European Parliament, also insists on the institution of a constructive dialogue between the parties interested in health and requests the convening of a quarterly forum, bringing together the representatives of the Member States, medical service providers, health insurance bodies, patients' organisations in order to debate the future of the European health protection system (EUROPEAN PARLIAMENT, ECONOMIC AND MONETARY COMMISSION, Draft opinion (provisional) aimed at the Committee on employment and social affairs on complementary health insurance, PE 285.513, 5th May 2000);