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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate G - Public Health

THE INTERNAL MARKET AND HEALTH SERVICES

REPORT OF THE HIGH LEVEL COMMITTEE ON HEALTH

17.12.2001

The High Level Committee on Health provides advice to the Commission services on matters related to the development of the Community's health strategy. This includes input on initiatives and activities in the public health field as well as on links between public health policy and other health-related policy areas. Moreover, it is a forum for the exchange of information between the Commission services and Member States' authorities. The Committee members are designated by the respective Departments of Health, and candidate country representatives are taking part as observers.

The High Level Committee created the working group on the Internal Market and Health in April 1999 with a mandate to

- collect information on the impact of Community provisions on health systems;*
- collect information on cross-border health care and service arrangements*
- identify the nature and degree of problems arising and consider options for Community and national actions to resolve them.*

A list of members of the working group is enclosed.

This final report was agreed by the working group in its meeting in Luxembourg on 19 September 2001. The Danish representative entered a general reserve to the report in the minutes of the meeting.

This report was discussed by the meeting of the High Level Committee on Health on 10/11 October 2001 and subsequently agreed in a written procedure.

‘Internal Market and Health Services’

Report of the High Level Committee on Health

Foreword and Summary

It is a common perception that health systems are entirely Member States’ area of responsibility. But in fact a wide range of Community-level legislation impacts on them in an unsystematic way.

The two 1998 Kohll and Decker rulings of the European Court of Justice (ECJ), and the very recent Smits-Peerbooms rulings of July 2001, have served to underline the point that Member States health systems, and in particular the delivery of health care, do not lie outside the jurisdiction of Community law.

In order to explore the impact of EU legislation on health systems, to understand whether, in the light of recent developments, a more proactive response was required at European level, and if so how this might be achieved in such a way that would be acceptable to Member States, the High Level Committee on Health set up a Working Group on the Internal Market and Health. The mandate of this group, of which this paper constitutes its final report, was as follows:

- Collection of information on the impact of Community provisions (Treaty and secondary legislation) on health systems, in particular access, flow of services, reimbursement mechanisms, financing of services and setting of overall health budget, quality of services, manpower planning, education and training of professionals
- Collection of information on cross-border health care and service arrangements
- Identification of the nature and degree of problems arising and consider options for Community and national actions to resolve them

The Working Group met four times. In addition to the results of the deliberations of the Group, the following report draws on two pieces of work in particular. First, a study by the Association Internationale de la Mutualité on the « Implications of recent jurisprudence on the co-ordination of health care protection systems », commissioned by

the Commission's Employment and Social Affairs DG and published in 2000. Second, the report of a BIOMED research project undertaken by the European Health Management Association (EHMA) which has explored the impact of EU legislation on national health systems.

This report is a first step in analysing complex issues and considering possible next steps.

It is organised in the following way.

An opening section summarises Community powers in health, considers the structure of health systems in Europe and discusses the possible tensions between the economic objectives of EU internal market regulations and the social objectives of the health sector.

Section Two describes current regulations governing the co-ordination of cross-border health services, the recent Court judgements which have implications for the delivery of care to patients, and provides an account of the experience to date in the European Union of cross-border care.

A third section details the impact of general EU legislation on the various sub-components of health systems.

The final section summarises possible future action against a set of principles which should govern future EU-level activity in this sector.

Section One

Health in the European Union

Legal framework

“Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices”. This is how the right to “Health Care” is described in the “Charter of Fundamental Rights of the European Union” agreed in Nice on 7 December 2000.

One of the tasks of the Community is “by establishing a common market and a monetary union to promote throughout the Community a harmonious, balanced and sustainable development of economic activities, a high level of social protection, the raising of the standard of living and quality of life and social cohesion and solidarity among Member States” (Art. 2 of the Treaty of Amsterdam).

According to Article 3 of the EC Treaty, the European Community has a broad policy mandate for health (“...the activities of the Community shall include... a contribution to the attainment of a high level of health protection...”) including specific tasks which are set out in Article 152 and other articles.

An important proviso is that Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.

Health is a fundamental part of the standard of living and quality of life. Health contributes to a harmonious balanced and sustainable overall development. Moreover, European citizens are concerned about health and are increasingly looking at the experiences right across Europe about how health is protected and how and in which quality health services are delivered.

This is a particular challenge in view of the Community’s forthcoming enlargement. In the process of preparing accession, formal negotiations have concentrated on the implementation of the *acquis*. The impacts on health status and health system both in existing and in new Member States have tended to be neglected. There is now a particular need to improve understanding about the effects of the internal market on health systems in candidate countries.

Health Systems in Europe

Health systems comprise many components all of which form sub-markets which are subject to Treaty provisions governing the free movement of goods and services. These include the market for medical manpower and the markets for pharmaceuticals and medical devices. Many of these individual markets are concerned with the *production of health care services*. As is outlined in Section Three below, all these markets have been affected in one way or another by Community legislation.

In addition, there is the *delivery of care to patients*, a potential market in cross-border care of patients which had been thought to be largely unaffected by Community Treaty provisions until the Kohll and Decker rulings of the ECJ.

An organisational typology of alternative models of EU Member States' health systems

There is a plethora of complex administrative and clinical arrangements under which patients obtain health care in the Member States, whose health systems have evolved individually over a long period of time and are based on very different organisational patterns and principles. Following the OECD classification, it is possible to discern six major sub-systems which comprise three sources of finance:

- Out of pocket payments
- Voluntary (or private) insurance premiums
- Compulsory (or public) contributions in the form of insurance payments or taxation funding

And three methods by which third parties can arrange for health care benefits to be provided

- Reimbursement of patients for medical bills which they have already paid (indemnity insurance) with no connection between insurers and providers
- Direct contacts with (often independent) providers to provide benefits in kind, usually with service-related payment systems
- Ownership and management of providers in an integrated model, generally lacking service-related payment systems

The health systems are sometimes referred to as Bismarckian where they involve social insurance and third party payers providing reimbursement insurance (Luxembourg, France and Belgium) or benefits-in-kind (Germany, Netherlands); or as Beveridge systems where funding is predominantly through taxation. In practice most EU health systems incorporate elements of all six systems, in different proportions and domestically many health systems are increasingly being devolved to the regional level. Given the wide divergences between Member States' health systems, their complete convergence has been seen as impossible in practice. Moreover, a number of key factors – concerns for the quality of services, fears of perceived external influences and general concerns about financing systems play a role in inhibiting a desire for increased harmonisation.

At present, therefore, there are neither legal powers nor recognisable political will within the Community to harmonise the delivery of health care in Member States.

Regulating Markets

The internal market regulations of the European Community are generally aimed at freeing up markets to obtain the economic benefits associated with free competition and reduced barriers to trade. However, health is not a typical market. The importance of health to the individual, and the need for Member States to ensure equitable access to health care across their populations, gives rise to a form of market which is not easily subject to the competitive model. For example, risk pooling, third party payment for taxation (through insurance funds or taxation) combined with the fact that historically patients have been dependent on the advice of medical experts to tell them what and how much health care to “consume”, means that patients do not purchase services in a conventional sense, and the scope for inefficient and inappropriate supply is much higher.

Under these circumstances, regulation can be an important tool for bringing about the desired social objectives and avoiding perverse incentives in an unfettered market.

It is generally accepted, therefore, that within the sub-markets of health systems, there needs to be extensive regulation of safety of health care goods and products, whilst pricing and reimbursement decisions by state authorities and other third party payers are carefully monitored and controlled in the interests of making basic health care accessible to everyone.

In this context the Treaty rules governing free movement of goods and services can appear to be rather blunt tools which require careful handling. The ECJ has itself recognised this point, noting in recent rulings that possible benefits to individual patients have to be weighed against the search for equitable access to care and for a secure local supply of services. Both these principles tend to militate against the movement of patients to other countries in large numbers. Furthermore, whilst many European health systems have in recent years seen deregulation and the development of organisational solutions mimicking the competitive market (the purchaser-provider split, for example) none of these experiments has proved entirely satisfactory.

Section Two

EU Legislation and the Delivery of Services to Patients

The Co-ordination of Social Security Payments Systems

There have been no EU initiatives to date to develop specific legislation on health care delivery issues in the Community. Nonetheless, a system of *co-ordination* of national social security systems has developed within the Community and is governed by Regulations EC No. 1408/71 and 574/72. These have their roots in the need to adopt social security measures necessary to facilitate freedom of movement for workers. They ensure that social security benefits are not lost when workers move from one Member State to another.

Regulation 1408/71 allows for reimbursement of costs for certain types of cross-border care. Frontier workers benefit from a double access to health care, both in the state of residence and in the state of work. To initiate this right in the state of residence (assuming that workers are insured in their state of work) an E106 form is issued. Moreover, individuals travelling abroad can gain access to health care in emergency situations. The E111 form is used to initiate the right to reimbursable health care in these situations.

Patients can also obtain prior authorisation to obtain medical treatment in another Member State (using the E112 form) which will be paid for, at tariffs prevailing in the *providing* state, by the competent institution in the state of insurance.

The application of these Regulations is governed by an Administrative Commission, which also negotiates agreements between Member States, resolves problems of interpretation and oversees the settlement of claims and debts between Member States. The latter are settled either in accordance with actual expenditures incurred, or on the basis on lump sum payments agreed by the Administrative Commission. Some Member States waive claims for benefits provided on their territory in compensation for claims against sickness costs of their own patients which have been incurred in other Member States.

While the system has been designed to cover the needs of migrant workers and people on short-term stays in mind, specific issues have arisen regarding retired persons who choose to reside or stay in another Member State. Many retired people coming from EU

countries stay long periods in southern Member States. Some of them haven't bought houses there to stay in these areas during the winter months. Many of these people suffer from chronic diseases that require medical attention and follow up or that may require hospitalisation due to relapse. They do not require emergency care, because their basic disease is chronic, and in general, they do not suffer from specialised conditions which would require prior authorisation.

Free Movement of Patients: recent developments

The Kohll and Decker rulings

In April 1998 the European Court of Justice made two rulings which many EU member states regarded as a major development in the application of European law to the field of health care. Mr Kohll, a Luxembourger, had taken his daughter, a minor, to Germany for orthodontic treatment and wanted a Luxembourg insurance fund (Caisse de Maladie) to reimburse that proportion of the cost of the treatment to which he would have been entitled in Luxembourg. Mr Decker wanted his (Luxembourg) Caisse de Maladie to reimburse, at Luxembourg rates of entitlement, the cost of a pair of spectacles purchased in Belgium. In each case, the Luxembourg insurance fund responsible for the claims had refused to reimburse the claimants on the grounds that, under existing European regulations governing the co-ordination of member states' social security schemes, they should have obtained priori authorisation (E112 forms) before seeking treatment outside Luxembourg. In both cases, however, the ECJ upheld the claimants' cases under existing Treaty provisions governing the free movement of goods and services.

To many Member States these rulings represented an attack on their right to organise their health and social security systems in their own way under *subsidiarity*. The ECJ argued, however, that this discretion could not be used to breach EC law.

The ECJ did not declare Regulation 1408/71 invalid, but argued that it did not provide an exhaustive list of the means by which an EU national could obtain medical goods and services in another Member State. The immediate impact of this ruling was to institute a dual system for obtaining reimbursement for cross-border health care, namely:

- under EC Regulation 1408/71, providing for the issue of forms E111 and E112, whereby costs are reimbursed in accordance with the scale of charges in the country of treatment;
- the new “Kohll and Decker option” whereby the insured person obtains treatment abroad and is subsequently reimbursed in accordance with the scale of charges in the country of insurance.

The Kohll and Decker rulings left considerable ambiguity about what were the specific areas of health care provision to which they applied. One important uncertainty was whether the rulings applied to hospital care or whether the requirement to maintain a

balanced national medical and hospital service open to all might provide a public health justification for not applying Treaty provisions to hospital services.

The second issue was that the majority of Member States, which do not operate the Luxembourg system of restitution insurance, were left in doubt about whether and how the Kohll and Decker rulings applied to their particular systems of health care provision and payment.

The Smits-Peerbooms rulings

The Kohll and Decker Rulings were followed in July 2001 by the Smits-Peerbooms rulings which have further clarified the application of European law to Member States' health systems. Mrs Smits-Geraets sought reimbursement from her Dutch insurance fund for reimbursement for treatment for Parkinson's disease which was received in Germany. Reimbursement was refused on the grounds that adequate treatment for Parkinson's disease was available through a contracted provider. The claimant argued that the quality of clinical care offered by the German clinic was superior to that available in The Netherlands.

In a separate case, Mr Peerbooms was referred for experimental neuro-stimulation therapy in Innsbruck, Austria for which he would not have been eligible in The Netherlands which currently reserves this treatment for patients under 25 years of age. Mr Peerbooms recovered full consciousness after the treatment in Austria. However, reimbursement was requested and refused on the grounds that appropriate care could have been obtained from a contracted provider.

In its judgements, the ECJ confirmed that all Member States must comply with Community law when exercising the power to organise their social security systems. The Court further confirmed that medical activities including hospital services fall within the scope of Article 50 of the Treaty (the freedom to provide services within the Community). However, the need to maintain the financial balance of social security systems and the maintenance of a balanced medical and hospital service open to all may justify a restriction such as is provided for under the system of prior authorisation.

The Court went on to comment on the conditions under which authorisation should be given under existing EU legislation. The treatment given should be regarded as "normal" in international professional circles, and must be required by the patient's condition. Authorisation can be refused only if the same or equally effective treatment can be

obtained *without undue delay* at an establishment having a contract with the insured person's sickness insurance fund. While the idea of 'undue delay' has not been completely defined, it should be noted that some Member States with lengthy waiting times for a number of medical conditions, may find it difficult to justify refusing authorisation for treatment abroad.

Cross-border patient flows: the experience so far

Total cross-border flows in the EU are summarised in the following table from the AIM report.

Table: Breakdown of claims linked to co-ordination policy and this figure expressed as a proportion of public health spending in Europe (in p.p.p.):

	1989 (mio €)	1993 (mio €)	1997 (mio €)	1998 (mio €)
Invoiced claims (E125)	352.2	756.5	598.3	613.3
Lump-sum claims (E127)	108.2	346.2	295.6	144.3
Total claims (1)	460.5	1.102.7	893.9	757.6
Total public health spending in Europe (p.p.p.) (2)	265.093	369.315	471.036	-
(1)/(2)	0.17 %	0.30 %	0.50 %	

The tables indicate that expenditure on cross-border patient flows amounts to 0.3-0.5% of total healthcare expenditures in the EU. However, the data is unreliable and incomplete since it does not include cross-border flows between Member States who prefer to waive the billing arrangements, nor does it capture purely bilateral arrangements, which are not effected through the EU co-ordination system. One very old (1990) analysis of the breakdown of expenditures showed that, whilst the majority of the volume of claims was accounted for by E106 forms (63%, compared with 33% for E111 forms and only 14% of E112 forms in 1988), the majority of expenditure was accounted for by E112, reflecting the much higher unit costs of E112, i.e. elective, inpatient, care. A distributional analysis,

conducted at the same time, indicated that only a few Member States accounted for the majority of expenditures on cross-border care. This seems to reflect the development of very specific geographical trends. The particular situation of Luxembourg with its limited health care infrastructure has been frequently noted. As a result, proportionately more Luxembourg residents receive authorised care abroad than residents of other Member States.

Regulation 1408/71 (Article 22) specifies the conditions under which authorisation for care abroad may not be refused; “when the treatment in question is part of the services provided for by the legislation of the Member State where the person concerned resides and when these services cannot be given within the period that is normally necessary, in view of his current state of health and the probable course of his disease”. However, these conditions leave considerable scope for interpretation. In practice, the choice of criteria governing prior authorisation decisions for medical care abroad was left more or less entirely to the discretion of individual Member States.

Experiences in easing access to cross-border care: cross-border co-operation between Member States

Bilateral Initiatives

Some Member States have concluded agreements making access to hospital treatment easier for their own nationals, or for those living in certain regions where there is insufficient treatment provision. For example, since March 1978, socially insured Dutch residents of certain regions in the south-west of the Netherlands have been able to receive medical care at the expense of the Dutch social security system in two Belgian hospitals at Gent and Bruges. The principle of territoriality of benefits has been waived in this region because of the limitations of its health care infrastructure.

Of all Member States, Luxembourg issues most E112 authorisations, again because of the limited health care infrastructures which can be supported by such a small population. In order to simplify administrative procedures for the reimbursement of costs, Luxembourg has drawn up agreements with medical establishments in the surrounding countries which bill the Luxembourg health insurance funds directly for treatment provided to Luxembourg patients.

There is also a bilateral agreement between Ireland and the UK laying down special arrangements for the reimbursement of medical expenses (excluding the costs of E112

referrals), and Germany has recently concluded an agreement with Norway to provide care to Norwegian patients.

Moreover, there are projects between different Member States to ensure recognition and interoperability of existing health and medical cards.

The Interreg Projects

In addition, in 1990, the European Commission decided to launch a special initiative, the Interreg Programme, to promote the economic development of the border regions which occupy 50% of Community territory and 10% of EU population. Measures eligible for financial aid included “measures to promote co-operation in health, particularly the sharing of resources and facilities on a cross-border basis”.

This initiative gave rise to a number of cross-border co-operative health care projects, some of which have now been formally evaluated. The first practical experience began in 1992 between Hainaut in Belgium and Nord-Pas-de-Calais, with meetings to learn about the health care system and access to it across the border. Several complementary projects were set up on the basis of available capacity. For example, Belgian HIV patients were treated in a specialised French clinic, whilst French patients received renal dialysis in Belgium. The final stage of this project was to set up a regional cross-border observatory with the aim of reorganising health care on a regional level on the basis of the needs of the area’s population.

The Euregio Meuse-Rhine project was set up to establish co-operation between the insurance bodies and hospitals at Liege, Genk, (Belgium) Aachen (Germany) and Maastricht (The Netherlands) in the border region between these three countries. Under the reduced authorisation procedures introduced, all people living in the experimental region qualified for basic medical care at the provider of their choice. A study of the project included an analysis of factors determining cross-border patient flows. In an extension of this project, the central Dutch insurance fund has established formal contracts with health care providers in both Germany and Belgium.

Under the Euregio Rhine-Waal project, situated in eastern parts of the Netherlands bordering Germany, patients living and insured in Germany could access certain specialities at the University Hospital of Nijmegen, for which they would have otherwise to travel a much greater distance in Germany. The Euregio Scheldemond is situated on the border between The Netherlands and Belgium in the Flanders region and its main

object was to improve access to health care across national borders in the region for frontier workers and their families. Since October 1997, the insurance organisations have been running information desks to inform citizens, workers and heads of business about the specific financial and administrative problems faced by the border regions.

There have been a number of other specific initiatives involving co-operation between hospitals, and several initiatives are underway using health telematics applications to facilitate cross-border health care provision.

General Lessons from the Euregio projects

In general, the take-up of opportunities for cross-border health care in these experimental projects has been limited and flows of patients demanding cross border care have been small. Patients tend not to travel across borders for health care, preferring to use a domestic system which is tried and trusted and operates in their own language. On the other hand, the difficulties of accessing domestic supply is seen as a potentially important factor driving patients abroad.

The initiatives tend to have certain common denominators:

- they generally involve advanced technologies such as cardiology, traumatology, emergency treatment, neonatology, dialysis and radiotherapy
- they depend on the existence of bilateral agreements
- they draw attention to the importance of involving insurance bodies and health care providers
- they increasingly involve citizens through forums and health observatories, information desks and training programmes for care providers

The projects demonstrate some important barriers to further co-operation between health care systems which are fundamentally different. These include:

- The need for quality assurance: clinical standards and protocols, accreditation of professionals to similar standards, accreditation of institutions
- Other non-clinical quality issues, such as guarantees for medical devices
- The importance of information for patients and referring clinicians

- The consistency of contracting and reimbursement procedures
- Questions of legal liability across borders
- The use of compatible telematics infrastructures

Disaster Medicines Initiative

In general, disaster medicine is dealt with in the context of Civil Protection but close co-operation with health policy is essential. In fact disaster medicine makes use of general principles in health care and operates through an upscaling process of the resources of the health care systems. In the context of the two Community action on civil protection (1998-99 and 2000-2004), the Commission's DG Environment has co-financed with the Netherlands a major project involving all Member States. The following objectives were attained in the context of the first phase of the project

- networking of specialists and structures of the Union in the field of Disaster Medicine (via an internet site) in order to stimulate and support co-operation in case of major accidents (points of contact, inventory of bilateral and trans-border agreements, definitions of methods to evaluate performance and quality, etc.);
- definition of a common training programme for trainers in the field of disaster medicine to be proposed at European level;
- establishment of guidelines for the practical implementation of psychosocial support actions for rescue workers and victims as well as for families and other non-victims present in an accident;
- the establishment of an action plan for future actions in this field.

The long term goal of the project is now to ensure that *«Struck by a large-scale accident or disaster, people living or travelling in European Union Member States should receive the same high quality medical care»*. The current project focuses on:

- cross-border mutual assistance between Member States
- follow up psycho-social care
- preparation for major accidents and disasters

In practice, policy papers and guidelines for publication and information dissemination will be developed around these core items as follows:

- in the field of cross-border assistance : common nomenclature, legal restrictions on personnel and equipment, communications, training needs, common badging

of emergency personnel, and expectations on the quality of the assistance. Practical exercises will help analyse the problems of cross-border actions.

- in the field of preparation for major accidents and disasters : development of performance indicators, quality of care, management of the medical chain and the development of scenarios. In parallel a policy paper will deal with common triage method as an essential part of the medical thinking in disaster situations.
- in the field of psychosocial care : help generate a professional network of experts - and a European guideline covering the organisation of this area.

The project serves also as a basis for the definition of the common rules pertaining to the implementation of the medical component of the newly established Community mechanism for the co-ordination of Civil Protection intervention in the event of emergencies.

Section Three

The internal market and health systems

It has long been recognised that a wide range of Community legislation has both intended and unforeseen impacts on Member States' health systems¹. While health considerations will have played a role in developing these actions, most have been undertaken as part of policy frameworks in other areas and not on the basis of the Community public health competence in Article 152 of the Treaty.

Most of the Community legislation which impacts on health systems has been developed in the general context of the completion of the internal market. This comprised a wide range of actions targeted at ensuring free movement of persons, goods, services and capital within the Community. The EHMA study referred to above concludes that 233 regulations, directives, decisions, recommendations and rulings of the ECJ related to the internal market issued between 1958 and June 1998 had the potential to affect Member States' health systems.

Related Community legislation, in particular in the social policy area, has also had important repercussions for health systems.

In terms of *free movement of goods*, specific legislation has been developed to cover products related to the health sector. In particular, there is Community legislation in place related to the authorisation, marketing and free movement of *pharmaceuticals*. This governs the establishment of approval procedures for new pharmaceuticals, with standards of safety and efficacy of new products, with patent and data protection standards and with standards for distribution and marketing. A European Medicines Evaluation Agency (EMA) has been created.

A system governing the certification and registration of *medical devices* has also been set up. This procedure relies on the agreement of standards and on the reciprocal recognition of authorisations granted in individual Member States.

¹ This section relates to the potential impact of Community measures on health systems. It does not cover impacts on health status which could e.g. derive from Community action in food law or in social policy.

It is obvious that an improving access for medicines and medical devices to the markets in Member States has had an important impact on the availability of these products, and on the capacity of Member States to regulate their supply.

A number of measures concerning *other products* have also been taken in the context of the internal market, concerning e.g. chemicals, dangerous preparations and radioactive products. These affect health services in a marginal way, insofar as these products are utilised.

Generally speaking, the principle of the *free movement of services* applies also to health services. This means that health service providers can offer their services in another Member State without any discrimination vis-à-vis national providers. While there is little evidence that this has happened to a large extent throughout the Community, it is possible that in border areas, mobile services such as home or day care, ambulance and transport services could be provided across borders. Moreover, a number of Community measures have been taken to ensure that producers of goods and providers of services from other Member States are not discriminated against. For example, Community law related to *public procurement* stipulates that public bodies are required to publish calls for tenders beyond certain thresholds at EU level. More generally, the Community's *competition law* could – under certain conditions – also be applied to health and social services.

The *free movement of capital* does not seem to raise any specific issues related to health systems.

A range of Community measures, however, is aimed at facilitating the *free movement of people*. Most importantly, a set of specific directives has been established governing the recognition of diplomas for individual health professions. This system, which is currently under review, is intended to allow health professionals (doctors, nurses, midwives, etc.) to take up work in another Member State while avoiding major difficulties related to registration and recognition.

Overall numbers for the mobility of health professionals remain limited. However, in some Member States and regions, recruitment of health professionals from other Member States has become routine practice. The facilitation of mobility in this area has changed the labour market for health professionals, opened new career opportunities for them and has allowed health services to draw from a broader base for employing staff.

Community legislation related to the *co-ordination of social security systems and health insurance coverage* in other Member States, discussed elsewhere in this report, has been developed to further facilitate the free movement of workers within the Community.

More generally, a range of Community measures taken in the *social policy* field can also be seen in this general context.

The *working time Directive*, for example, contains provisions fixing maximum working time in a given period. An initial exemption for junior doctors in hospitals has now been abolished. This has had extensive repercussions for the organisation of work in health services in some Member States and has resulted in remarkable improvements in working conditions for hospital doctors in particular.

In addition, a body of Community legislation has been developed in the area of *health and safety at work*. Apart from its general application in relation to health services, in some Member States, this has even resulted in the creation of an occupational health branch within the health system.

It is clear then that Community initiatives are having an important impact on health systems. But these activities are taken within the framework of creating and improving the functioning of the internal market. It is not surprising, therefore, that they have not been developed in the context of a clear and coherent health policy. This is the reason why some important health policy concerns of Member States have not been taken on in this framework. In particular, issues relating to quality and effectiveness of goods and services (as opposed to issues of safety), have been largely absent from legislation so far. This contrasts with the ECJ's insistence, in the Smits-Peerbooms cases, that recognised standards of medical treatment should be taken into account when deciding about granting authorisations for treatment abroad (see above). In a similar way, the quality of training of medical staff (let alone issues related to further training on the job) is not covered in current legislation.

Moreover, while there will always be repercussions of general legislation on specific sectors, it is a remarkable feature of the health sector that core aspects of health policy – such as policies on health professions and on medicines – are not yet regarded as an integral part of the Community's health agenda. This points to the need to develop a more coherent and comprehensive Community approach to health, as emphasised in the May 2000 Communication on the health strategy of the European Community.

Section Four

Towards a Comprehensive Community approach:

Conclusions and Recommendations

The Situation

Member States acknowledge that health is an area where the Community has an important role. But at the same time, health care systems are an essential part in national economies, accounting for between 5% and 10% of GDP. For that reason, some Member States argue that the scope of health policy at EU level as it affects health care should be fairly narrowly defined. . In particular, they oppose the idea that health policy at EU level should cover matters concerning health care systems and health services.. In doing so, they place emphasis on the limitations built into the public health Article (152) of the Treaty as well as the principle of subsidiarity.

Over the past few years, health policy has been rising in prominence on the Community's policy agenda. This is demonstrated inter alia by the widening of the Treaty provisions in this area and by the fact that there is now a Commissioner responsible for health and consumer policy and a corresponding Directorate-General, even though at the same time, there are other Commission services dealing with health-related matters. Nevertheless it is clear that health policy at EU level is still in its infancy and it has not yet been given the priority it requires in policy-making within EU institutions.

The development of a proactive and broader health policy under which the main health interests will in future be dealt and co-ordinated is a priority for the immediate future. Until this happens, Community measures which impact on health will continue to be largely influenced and dominated by economic considerations and factors and not by health policy interests.

National governments have been slow to recognise the impact of the EU on health policy; this has been accompanied by a relative lack of interest in single market influences on their health care systems.

These influences are the inevitable consequence of European integration. They will therefore continue as part and parcel of this process, and their consequences may well gain in importance. The impact in each Member State will, however, vary in extent because of the different organisational settings of health services, as well as countries' geographical settings within the EU. This will be of particular importance for Candidate countries.

The Community, when preparing single market interventions, has tended to neglect intended or possible unintended effects on the different health care systems, not least because health ministries have not tended to interest themselves greatly in these areas.

Lack of consensus, and consequent inaction at a political level, mean that more and more issues have been decided by the European Court of Justice which is therefore put in the position not only of interpreting the Treaty but de facto of making health policy by defining the influence of EU regulations on health care.

General Aims and Principles

The following aims and principles could guide further actions and discussions.

- The starting point is to acknowledge that EU Internal Market regulations designed to ensure the free movement of persons, goods, services and capital within the Community, apply to and impact on health care services.
- It is essential:
 - to raise the profile of health policy at EU level
 - to bring key policy areas hitherto regulated in an internal market context into a health policy framework. This would include healthcare issues
 - To ensure that this framework takes account of the need for Community added value on the one hand, and of Member States responsibilities on the other.

- There is a need for a clearer understanding of the principles underpinning Member States responsibilities, in the light of the recent developments outlined in this report. These could include, for example, full responsibility for:
 - How their health care system is funded (e.g. tax based or insurance based)
 - What package of care is to be publicly funded
 - The total level of public expenditure on health care and how it is allocated (e.g. centrally, Regionally etc)
 - How demand is managed to keep within planned resources

- At the same time, health should be integrated into general Community strategies such as sustainable development and the “Lisbon process”. The open method of co-ordination is one tool for achieving this.

- Internal Market rules should be designed to take full account of the interests of patients and health services rather than only economic interests. A greater clarity about the impact of EU legislation on health care systems therefore has to be established to avoid the danger of developing policy without adequate evidence. This should become a particular focus of interservice co-operation on health issues within the Commission, lead by the Health and Consumer Protection DG.

- National health care systems will have to be fully compatible with EU regulations. This is a particular challenge for Candidate Countries. The full responsibility for achieving this remains with the Member States. However, an exchange of views and a common approach could stimulate this process.

Future Action and Instruments

What is important now is not to try to reach any definite conclusions – at this stage that would be premature - but to launch the debate, and to set in motion a process of discussion, reflection and exchange of views and information in our own countries and at

EU level. There is some urgency for this, due *inter alia* to key developments such as the upcoming discussions on Treaty reforms and further cases pending in the European Court of Justice. The High Level Committee could act as one focal point for this, but there would also need to be discussion in other fora, including by Health Ministers and by the European Health Forum. At the same time, a similar process should take place within Member States.

Listed below are a number of possible actions to take the work forward. Some of these are essentially for Member States to consider or are for bilateral co-operation, while others require initiatives at the Community level; some are fairly specific and uncontroversial, others are much more wide-ranging and potentially of considerable political sensitivity. Some of these build upon existing work or may indeed already be ongoing in some Member States. They now need to be analysed on the basis of experience and information.

- Consider how Community legislation, including a review of Regulation 1408/71 and the direct application of internal market law, could provide easier access to cross border health care. Initial work on this has commenced. This is a particular concern in border areas where bilateral agreements play an important role. Within this process, there is a particular need to consider the scope of the package for which authorisation cannot be refused. Areas to be addressed in this context could include outpatient care, specific pathologies, excessive waiting times and border areas.
- Promote convergence and coherence between Member States in relation to cross-border care, e.g. by supporting exchanges of information and improving data.
- Support cross-border projects, especially at a regional level, in border regions for certain services such as (specialised) hospitals, emergency/ambulance services, disaster co-operation by:
 - developing standard guide-lines
 - evaluating ongoing projects
 - providing patients with all needed information
- Implement the method of “open co-ordination” for health, as defined by the European Council, by: defining targets and objectives on the European level, defining,

quantifying and qualifying indicators and benchmarks, and monitoring, analysing and evaluating the achievements in the Member States.

- Consider developing a system of European centres of excellence, especially for highly specialised medical treatments, as well as new and experimental therapies. Initial steps to prepare this would include making:
 - inventories of Member States' needs, existing centres and their capacities
 - analyses of future needs
 - analyses of legal barriers and constraints
- Consider to develop a framework for a definition of common quality standards and best practice at Community level, including a Community reference framework – rather as an incentive than a normative one – which could cover quality standards, criteria for good medical practice, rules on equivalence of competence and medical practice, hospital accreditation, medical prescription, etc.
- Consider any actions needed to ensure that there are arrangements for transferring patient and clinical information in a reliable way which safeguards confidentiality; and ensure that the potential of telematics (e.g. health cards) is used to support these arrangements.
- Make full use of the possibilities of the new Community public health programme to underpin these proposals by supporting relevant actions.
- Obtain the advice of the newly created 'European Health Forum' in order to include the views of the public health community.

In addressing all these concerns, there may well be a need to consider a reformulation of the EU competence in health, with the objective of moving all related health powers into one Treaty Article as a means of further clarifying roles and responsibilities.



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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate G - Public Health
G1 - Policy analysis and development; international questions

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