ARE HEALTH SYSTEMS NATIONAL?

by

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ARE HEALTH SYSTEMS NATIONAL? – PERCEPTIONS AND REALITIES

INTRODUCTION

The question of whether health systems are national will be answered using a two fold approach:

1. An examination of EU health / health care policy through an examination of Treaties and Directives that affect:
- Health professionals
- Consumers
- Health services and EU competition policy
- Pharmaceuticals/ medical devices
- Voluntary health insurance

2. An examination of a group of multinational companies active in the health care sector that are likely to benefit from further liberalisation.
- Aetna/ING
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A. EU HEALTH AND HEALTH CARE POLICIES

This section on EU health and health care policies is based on a report "The Influence of EU law on the social character of health care systems in the European Union" by Elias Mossialos, Martin McKee, Willy Palm, Beatrix Karl, Franz Marhold, submitted to the Belgian Presidency of the European Union, Brussels, 19 November 2001.

Historically health competences at EU level have been developed to promote a common market. Other aspects of health policy have evolved as a result of policy developments in related fields. For example, occupational health and safety regulation have set uniform standards for a single European market. Food safety has dominated the agenda recently as a result of trade policy initiatives and public health concerns. Health care has been most strongly influenced by the concept of subsidiarity with national governments considering national health care systems to be their own responsibility. Health policy has traditionally been caught between the EU Treaties implemented through European legislation and the European Court of Justice (ECJ), and policy making which has been consensual between member states.

The original Treaty of Rome introduced 2 political dynamics towards integration:
- positive integration which involved establishing common policies which are approved by the Council of Ministers
- negative integration which was concerned with the elimination of national barriers to free movement of goods and services within the Community.

The European Court of Justice (ECJ) has played a prominent role in eliminating barriers to the free movement of goods and services and has also contributed to the definition of broader social policy issues such as gender equity and social protection.

The ECJ was set up in the 1960s for individuals to:

a) defend their rights against other individuals and legal entities (e.g. companies)
b) defend their rights against the state.

The state became responsible for national infringements of EU directives and in the event of conflict, national law was to cede to European law. Legal decisions have had a strong influence on the policy process. Policy makers have to take account of legal rulings, policy advocates have to look for legal rules to achieve objectives and policy reformers use case law to alter the impact of EU policies. Recently, the ECJ has had an influence on health policy in the fields of health care, medicines, environment, workplace health and safety and pharmaceuticals/ distribution.

Key points

- No coherent EU health/ health care policy
- Strong influence of subsidiarity principle on health care systems
- Dominant role of European Court of Justice (ECJ) in shaping health policy

EXISTING EU POLICIES THAT AFFECT HEALTH

The first European health policy was defined in the European Coal and Steel Community (ECSC) treaty with the establishment of joint research and cooperation in relation to health and safety of workers. The Single European Act of 1986 established an extension of the Community actions in relation to health although health policy was not treated as a separate policy area. It did extent the scope of occupational health and safety, and environmental and consumer protection. One of the aims of the Single European Act was to establish a system of mutual recognition of professional qualifications, which would include doctors. The qualifications of doctors have been recognised in a series of Directives in 1975, 1986 and 1995.

The Single European Act also led to the establishment of the European Medicines Evaluation Agency (EMEA) which is a quasi regulatory body dealing with regulating market authorisation requirements for medicines, advertising and packaging, labelling rules, and information content of inserts in pharmaceutical products.

The Treaty of European Union (Maastricht Treaty) of 1992 amended the Treaty of Rome with a formalisation of the powers relating to health care. Article 3(o) "contributes to the attainments of a high level of health protection". Article 129 dealt with public health and the prevention of disease and provided a framework for working towards health protection. Article 3(b) established the principle of subsidiarity especially in relation to health care, which has effectively limited the Community's role in health.

The Treaty of Amsterdam resulting from the Intergovernmental Conference of 1997 and finally ratified in 1999 has a specific Article 152 relating to public health. It states "Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating scourges of danger to human health". It also states "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". There was also a reassertion of the subsidiarity principle in relation to health care systems.

As a result of agreeing Article 152, a new Directorate was set up for Health and Consumer Affairs, which drafts proposals for legislation. The European Parliament deals with health issues

through the Committee for Environment, Public Health and Consumer Protection. Health policy actually cuts across all directives and there is no coherent health policy strategy.

Any new EU health care policy will require a new Treaty. It will also depend on public health being considered in a wide sense with the determinants of health addressed as well as health care needs of the population. Wider health policies that address both the determinants of health and health care are only slowly being developed at national level.

Key points

- Single European Act and free movement of professionals
- Foundation of the European Medicines Evaluation Agency (EMEA)
- Treaty of European Union 1992 – health protection
- Treaty of European Union stated the principle of subsidiarity and the responsibility of Member states in relation to healthcare
- Treaty of Amsterdam Article 152 – public health and prevention of diseases and reassertion of subsidiarity principle
- Health policy cuts across all policy areas but lack coordination

EFFECTIVENESS OF EXISTING POLICY ARRANGEMENTS

This section will examine the effectiveness of existing policy arrangements in relation to:

1. Health professionals
2. Consumers
3. EU Competition law and health care systems
4. Pharmaceuticals
5. Voluntary health insurance

1. HEALTH PROFESSIONALS

Health professionals through their professional organisations play a role in determining the scope and nature of professional training, establishing the framework for continuing education and monitoring quality of clinical performance and ensuring the application of high ethical standards. These responsibilities are undertaken at national level and the mechanisms used vary according to the history of the institutions involved and the relationship between health professionals and the State.

The Directives relating to free movement of health professional are based on a provision for mutual recognition of qualifications. Educational programmes have to comply with basic standards, which are usually defined in relation to length of training. Health professionals are considered to have reached the level of competence to work anywhere in the EU once they have completed a series of qualifications, defined by length of training.

The aim of ensuring free movement of health professionals was to balance the surpluses and deficits of health personnel that exist within the EU. However there is a suspicion among national regulation bodies that qualifications are not equivalent because of less direct patient contact and practical experience during training. As a result, illegal forms of discrimination still operate. A further limitation of the Directives is that they do not cover health professionals qualified in a Third Country but registered in Member state. New legislation is planned that will address this limitation by considering cases on an individual basis.

There is little evidence to show that the Directives have led to a freer movement due to cultural, social and institutional differences as well as language. The Directives focused on free movement at the expense of quality.

Key points

- Health professionals play key role in regulation but extensive national differences
- Directives focus on length of training and not quality of treatment and care
- Surpluses and deficits in health personnel have not been addressed by the recognition of qualifications

2. CONSUMERS

There are two grounds for receiving treatment in another Member state:

a) certain groups e.g. pensioners, self employed, frontier workers, students and families
b) urgent treatment required

Few use the system to receive "urgent" treatment because of obstacles such as language, distance, lack of information about other systems, unwillingness of doctors to refer patients, administrative burdens and travel time and costs. There is demand for cross-border care in border areas or in small states, which often involves high technology care. Only a limited number of people with access to adequate information get cross border care. Lack of information is a major barrier.

However, it is expected that the demand for cross border health care will increase in future. This is due to increased movement of people in Europe. In addition the increased shortages of human and financial resources in the health care systems that result in waiting lists, development of new experimental treatments, increasing information shared between patients, growing integration of border areas, increasing ability to compare prices resulting from monetary union and likelihood of more cases before the ECJ will all contribute to more patients obtaining treatment in other EU countries.

Patients are being supported to be more active consumers through:

a) health care providers who are better informed and trying to stake own position in the market
b) health insurance bodies trying to offer better services at lower cost
c) politicians and the media trying to raise awareness of different levels of provision as a way of pushing low spending states to increase health care expenditure.

Several cases have been taken to the European Court of Justice that have made cross border care a controversial issue for national governments. Recent judgements of the ECJ have shown that social security systems are not exempt from competition law. An outline of the key cases follows. They illustrate some of the arguments that are used to decide whether health care is an economic or social activity.

Kohll and Decker rulings April 1998

Two individuals insured under the Luxembourg social security system went for treatment in neighbouring countries and applied for reimbursement from their social security funds after they received treatment. Kohll requested authorisation for orthodontic treatment before he received treatment and was turned down because it was argued that the treatment was not urgent and could be done in Luxembourg. In response, Kohll argued that the prior authorisation procedures restricted him from "purchasing services" in other European Member states and so contravened Article 49 and 50 of the EC treaty. Decker who did not apply for prior authorisation, argued that the prior authorisation procedures restricted the freedom of movement of goods within the EU and so violated Article 28 of the treaty.

The European Court of Justice (ECJ) argued that the rules of social security systems were not exempt from rules for the free movements of goods and services and that Member states must comply with Community law when exercising the right to decide how to organise social security systems.

The Luxembourg government argued that prior authorisation was needed because:

a) To ensure a financial balance of the social security system and to enable government to provide a balance of medical and hospital services open to all individuals
b) To protect the public health of the population since there was no way of ensuring the quality of goods and services in other Member states
c) To enable the government to provide balanced medical and hospital services open to all insured people.

The ECJ dismissed these arguments because:

- Kohll and Decker had only requested reimbursement according to Luxembourg tariffs and therefore the Luxembourg government was no paying more
- The ECJ also ruled that the Luxembourg could not demonstrate that public health was threatened.
- According to the mutual recognition of qualifications an optician in one Member state must be equivalent to an optician in another Member state

This last point has been criticised in that it cannot be assumed that there are similar standards of care and also contradicts EU initiatives on accreditation and revalidation.

The implication of these rulings is that the ECJ appears to have established a dual system of social protection for non-urgent health care received in another Member state. On one hand, the ECJ upheld the classic E112 procedure in which a patient received prior authorisation accepted by a social security system in another country as though insured by it. On the other hand, the ECJ created an alternative (Kohll and Decker) procedure in which patients receiving treatments abroad without prior authorisation are not integrated into the social protection of the other State but can claim reimbursement from their own social security system as if they received treatment there subject to conditions and according to tariffs there.

The rulings also raised questions about whether they were applicable to:

- hospital and outpatient care
- all types of health care system (not just those operating reimbursements)

Following the judgement only Luxembourg, Belgium and Denmark amended their legislation for unconditional reimbursement of certain outpatient services and health care products purchased in another member state.

Smits-Peerbooms July 2001

A further case (Smits-Peerbooms) has helped to clarify some aspects of the Kohll and Decker ruling. Mrs Smits and Mr Peerbooms were both insured under the "benefits in kind" system in the Netherlands where permission to obtain treatment from non-contracted health care providers abroad is only given if:

a) The requested treatment falls within the scope of what is seen as "usual in the professional circles concerned"
b) The required treatment is necessary and not available without undue delay in the Netherlands

Mrs Smit received multidisciplinary treatment for Parkinson's disease in Germany from a specialised clinic without getting prior authorisation. She paid the clinic directly and asked for reimbursement from her Dutch sickness fund according to the procedure set in place by the Kohll and Decker ruling. The Dutch Sickness fund refused to pay arguing that the treatment was no "usual" and that the treatment was available from a Dutch provider and the treatment in Germany did no provide any additional advantage.

Mr Peerbooms went into a coma after a car accident aged 36. His neurologist moved him to Austria where he received intensive neuro-stimulation therapy and recovered full consciousness. This therapy was only available in two institutions in the Netherlands for people under 25. The payment was refused as the sickness fund argued that there was appropriate care available in the Netherlands.

Mrs Smit and Mr Peerbooms took the case to the ECJ and claimed that they were entitled to the costs of treatment under EC rules on the free movement of services. The ECJ had to decide:

a) Whether the EC Treaty provision on the free movement of services applied to health care provided in hospital
b) Did the requirements for prior authorisation for hospital treatment abroad go against the treaty provision
c) Whether the Dutch system of authorisation could be justified

The Member states argued that:

1. No remuneration within meaning of Article 50 when patient received treatment without paying for it (as benefit in kind) or where all or part of the amount paid was reimbursed
2. To be an economic activity the person providing the service must be aiming to make a profit
3. The social security system is not an economic activity as people using it are unable to decide the content, type and extent of the service and price to pay

The ECJ did not uphold these arguments and reaffirmed that medical activities do fall within scope of rules on freedom to provide services and that there is no need to distinguish between hospital and non-hospital services. Smits and Peerboom did pay the hospital first even though they applied for reimbursement. The ECJ noted that a service did not have to be paid for directly for it to be classified as a service. As hospitals are paid for the services they provide, the ECJ concluded that treatment in a foreign hospital was a service in the sense of the EC treaty.

The ECJ found that the need for prior authorisation for treatment abroad would deter insured people applying to providers in another Member State and so constitutes a barrier to the freedom to provide services. However a barrier could be justified in the following circumstances:

1. Where there is a risk of undermining the financial balance of the social security systems
2. Where the objectives of balanced medical and hospital services are threatened
3. Where maintenance of treatment capacity is necessary for public health and survival of the population

However the ECJ found that such exemption to principles of free movement of services was only acceptable if the system of prior authorisation proved to be necessary and proportional and was based on objective criteria that did not discriminate against providers established in another state. The package of benefits covered by a social security system must be defined in the light of Article 30 EC Treaty "objective criteria without reference to origin of products" and that decisions to grant or reject prior authorisation must be given in reasonable time and be capable of challenge in judicial/ quasi-judicial proceedings.

The implications of these rulings show that economic rules relating to the free movement of goods and services can be applied to social security systems including hospital services and all types of health care systems (reimbursement and benefits in kind). There are two major unresolved issues:

a) An expectation that there is a consensus across Europe on what treatments should be covered and evidence based but this does not recognise that national health beliefs and treatment patterns are diverse

b) There has been no definition of "undue delay". The Smits-Peerbooms case ruled that national authorities have to take into consideration the patient's medical condition and past medical record. This has implications for patients on waiting lists.

Key points

- Cross border treatment likely to expand in future
- The Kholl and Decker ruling created alternative arrangements for patients claiming reimbursement of treatment received in another country
- Smits ruling clarified that the system of prior authorisation had to have clear criteria
- Rulings show that economic rules can be applied to social security systems
- Several unresolved issues e.g. lack of consensus on treatments

3. EU COMPETITION LAW AND HEALTH CARE INSTITUTIONS

The extent to which health care institutions are subject to EU competition law depends on whether they can be defined as "undertakings". An undertaking is "an entity that engages in economic activity, regardless of its legal status and the way it is financed". An entity does not have to make a profit to be considered an undertaking and so non-profit and charitable institutions can be considered as undertakings. Associations of organisations can also be undertakings.

One of the criteria for considering a health care institution as not being an undertaking is whether its activities are "sovereign", social, non-remunerative and solely to meet need. "Sovereign" activities are those pursued by the State exercising official authority. The key point is whether the activity must necessarily be carried out through the exercise of official authority. It is not a sovereign activity if the institution also trades products alongside private undertakings seeking to make a profit.

The definition of social activity has emerged from a series of court rulings. An activity has to be assessed individually to see whether it is social or economic. If a health care institution operates in a way that would preclude a private company, if working in the same way, from making a profit, then this might be called a social rather than an economic activity. It is an activity that is governed by principles of solidarity and social protection.

A purchaser of health care is subject to different considerations. If a purchaser purchases health care on behalf of a population then this will reflect economic and not social concerns even if the goals are social. The key issue is whether the institution engages in economic activity in the same way as a private undertaking. It may be able to argue that it performs the task in the "general interest" and would be hindered in doing so by the application of competition law. The provision of health care benefits when no identifiable payment is made, is not considered to be subject to legislation relating to freedom to provide services or legislation relating to competition.

EU competition law forbids cartels. All agreements between undertakings, association of undertakings and other practices that might interfere with competition are prohibited. This applies to horizontal and vertical agreements. EC law also takes into account the scale of the impact of restraint on competition. The restricted admission of panel doctors is unlawful where the selection process is arbitrary or abusive.

Services of general interest include health and social protection. If these institutions become active in economic terms then they can be said to provide services of general economic interest.

If the application of competition law stops or obstructs heath care institutions from performing their tasks then they may be exempt from the provisions of competition law.

Public procurement directives only cover contracts over a certain value. It covers contracts awarded by State, regional (and local) authorities and institutions governed by public law and associations that consist of several of these types of institution. These apply to health care institutions when they purchase for their own needs e.g. equipment or buildings. Contracts for medical services are more difficult to classify in systems providing benefits in kind.

Health care institutions may be subject to competition law. The key question is whether they engage in economic activity. Each activity has to be judged on its merits. However, the results of health care reforms may mean that with the introduction of market mechanisms and decentralisation, health care institutions are more vulnerable to being considered subject to competition law. To counter this, the EU needs a set of principles to inform health policy in order to meet the health care needs of its population.

Key points

- Health care institutions as "undertakings" and exemptions defined by sovereign, social, remuneration and coverage of need criteria
- Exemption from services of general economic interest
- Health sector reforms make it more difficult for health care institutions to be considered exempt from competition law

4. PHARMACEUTICALS AND MEDICAL DEVICES

The EU is involved in policy in relation to pharmaceuticals and medical devices in two ways:

a) Through market authorisation and the Community's attempts to harmonise and standardise, at EU level, guidelines and approval procedures that fulfil health and safety criteria while meeting the interests of Member States, European Commission, consumer/patients and relevant interests – equitably.
b) To facilitate the free movement of products within the internal market in relation to competition and industrial property rights

The level at which regulation takes place depends on whether an industrial policy and health policy perspective is taken. Industrial policy has wider harmonisation powers than health policy. The regulatory frameworks for medicines and for medical devices are very different with that for medicines developed since 1965 and for medical devices since 1990. The medical devices regulatory framework has been driven by the aim of increasing cross border trade whereas that of medicines was triggered by public health concerns.

Pharmaceuticals

The pharmaceutical framework has developed unevenly because pharmaceutical policy brings the principle of subsidiarity into conflict with the requirements of the single market. Pricing and reimbursement of medicines remain national concerns. The European Commission is also interested in maintaining a strong pharmaceutical industry and wanting greater harmonisation of national systems. It has up to now failed to address prices and reimbursements of pharmaceuticals.

There are pharmaceutical policies on labelling and packaging, advertising sales and promotion, wholesale distribution, which all reflect priorities of the single market. The creation in 1995 of the European Medicines Evaluation Agency EMEA has taken elements of market approval away from national regulators. The creation of EMEA is the first office with a regulatory mandate. It gathers and disseminates information and proposes decisions that, when endorsed by the Commission, create Community policy.

Criticisms of the agency's work focus on its lack of transparency, which means that it can be subject to influence from the industry. There is a lack of clarity about the balance of consumer and industry needs. Although the Agency's website provides access to a wide range of information about decisions, this has been criticised as opaque and inaccessible. There are also criticisms about whether the Agency serves the interests of the industry rather than public health and the consumer.

Pricing controls are the responsibility of the Member states. Although the EU does not have a direct role in pricing of drugs, some rulings by the ECJ have had an indirect effect. In 1984 the ECJ in the Duphar case enabled Member states to organise their health social security systems in a way that sustained financial viability. Choice of medicines excluded from reimbursement must meet certain objective criteria. This case also ruled that national controls on doctors' consulting behaviour was consistent with the Treaty of Rome.

The Transparency Directive 89/105/EEC aimed to ensure open and verifiable criteria in national pricing and reimbursement decisions. This was to ensure the function of the single market. There was some Member state opposition to this Directive because it was felt to infringe on Member states sovereignty.

There are price differentials between Members states for medicines. These differences are allowable in the internal market. This has resulted in a parallel trade, which involves the purchase of branded medicines in one Member state and their sale at below the market prices in another more expensive Member state. A distributor buys drugs from wholesalers in cheaper countries and exports them to more expensive countries where they are sold to local wholesalers. This can result in cost cutting of health care costs and so several Members states have supported it. This parallel trade can limit industry profits and promote competition.

Direct to consumer (DTC) advertising is currently illegal in Europe. There are mixed views about what impact the introduction of direct-to-consumer advertising would have, although as patients are getting information from American websites, it is felt that it would be better if they accessed it from Europe. As a result, a five year pilot programme for disease awareness programmes for specific disease areas e.g. AIDS, diabetes and asthma, is being introduced. Pharmaceutical companies can make information available on request from patient or consumer groups. Health activist groups have opposed this due to the results of direct to consumer advertising in the US where it has led to a distortion of prescribing behaviour and companies marketing only newer more expensive drugs. It appears that the Commission is moving towards the liberalisation of pharmaceutical advertising regulations in Europe.

Medical Devices

Medical devices cover a wide range of treatments, terminology varies from country to country and there is no single medical device industry. There are four main sectors: medical-electrical devices, non electrical products, implantables, diagnostic products. There is now an EU definition of a medical device which will contribute to regulatory frameworks in future.59

Medical devices do not have a central regulating agency and market authorisation is not so regulated. Devices are only required to carry a CE mark (Conformite Europeen), which shows they conform to standards required for sale in the EU. However the CE legislation has been adapted in different ways by national governments, with some incorporating all the legislation word for word, with others adapting it to their own legislation. The CE Mark relates to the manufacturer's own judgement about how the product meets minimum standards.

The medical devices do not have a central agency but the Medical Devices Directives (MDD) do provide a regulatory framework for the industry. They have been criticised because of

concerns about safety controls in some areas, rapid changes in the device industry and related technology, and the proposed enlargement of the EU. There have also been questions about the transparency of the framework.

Key points

- EMEA still does not address pricing and reimbursement of medicines
- Parallel trade in medicines
- Direct to consumer advertising – pilot introduced
- Medical Devices Directives do not address safety controls or rapid changes in the industry
- Enlargement of EU raising issues for regulation of both pharmaceutical and medical devices industries

5. VOLUNTARY HEALTH INSURANCE

Health insurance is considered an economic activity and so subject to laws relating to the single market. Since 1970, at a European level, there has been a single market for life and non-life insurance. It has set up a legal framework to ensure the development of private insurance in an integrated market, which stimulates competition, increases choice and protects consumers from financial loss. Although there is a European single market for non-life insurances, the position of voluntary health insurance is unclear because different definitions of social security exist in different countries. Statutory health protection and the way in which it is organised influences the demand for voluntary health insurance.

There is a lack of clarity about the scope of the Directives and the type of operators covered by the Directives. This applies particularly to mutual health funds, which often have a wider role than just insurance and this makes them different from private commercial insurers. There are increasing conflicts between mutual funds and private insurers because of the growing need for complementary or alterative health insurance cover. If mutual funds are seen as equal to commercial providers then the "good risks" will be taken by the profit motivated companies and people with higher health risks will be forced to pay increased premiums.

Mutual funds are often given a special status by national law acknowledging their comprehensive role including health promotion/ prevention, social cohesion, solidarity and reducing health inequalities. A special status often results in tax advantages. Private insurers are challenging these arrangements because they see them as market distortions and unfair competition. National governments are being pressured to eliminate these advantages.

Voluntary health insurance is now considered to play an important role in many health care systems. Extra regulatory developments are considered necessary so that the market for voluntary health insurance works efficiently and allocates resources in an equitable way. A recent Resolution adopted by the European Parliament calls on the Commission to examine the possibility of a framework for supplementary health insurance schemes. It recommends some basic minimum standards in relation to prohibition of use of medical data, prior medical screening, lifelong insurance, transparency as to changes in premiums, organising a pooling system to cover the cost of serious disease.

The resolution also calls on the need to develop a common view of universal services in the light of the Amsterdam Treaty. This might also involve a fourth generation of Insurance Directives that create a wider regulatory environment for human and social risk type insurance that would cover all insurers in order to prohibit selection of risks, to offer permanent health insurance and rule out possibility of cancellation of contracts due to age or state of health.

National governments can no longer regulate prices or conditions of insurance products because this would hinder competition among European insurers. This also limits the ability of governments to promote voluntary health insurance based on solidarity principles. More coordination between the different policy areas is needed. This is another example of the impact of the internal market regulations on health care.

Key points

- Position of voluntary health insurance is unclear in the wider insurance directives
- Voluntary health insurance now seen as integral part of health care system
- Threat to mutuality from implementation of existing insurance directives
- Future Directive likely to clarify position on voluntary health insurance

CONCLUSION

There is an urgent need for a EU health (and health care) policy. The present mix of policy initiatives and ECJ rulings that shape health care policy are no longer feasible if they are to address the health care needs of the population. The lack of a specific health/ health care policy leaves health care systems vulnerable to competition law and subject to the functioning of the internal market. Member States can no longer argue that health care systems should only be subject to the principle of subsidiarity. This is inadequate to address the health care needs of people in future. The existing Articles addressing public health are not strong enough to influence wider EU policies.

Until now, the EU has been seen as primarily working towards the development of the internal market and economic growth. The Treaties all address the movement towards a single European market. Both legislators and the European Court of Justice (ECJ) have focused on the promotion of the free movement of goods and services.

A new Treaty will be needed that defines a European wide health and health care policy. The new system of enhanced cooperation, designed for the promotion of social protection (pensions and social inclusion) may provide the basis for a future Treaty revision to address health care. Arguments that recognise the links between economic growth and the health of the population and health care systems are becoming more widely heard. They could be used to strengthen the case for including health and health care within a new Treaty.

B. MULTINATIONAL COMPANIES

A series of short case studies follow that highlight activities, geographical scope and future strategies of a group of multinational companies active in the health care sector.

AETNA/ ING

Aetna International, a US insurance company with an international division, was taken over by ING, a global provider of financial services in 2000. ING deals with banking, insurance and asset management in 65 countries worldwide. ING provides life insurance and pension products as well as insurance for health, accident and disability in several of its core markets in Europe, Asia and the Americas.

Aetna Financial and International services are being integrated into ING Europe, ING Americas, and ING Asia/Pacific. ING Europe is seen as ING's most important region. It is active in the Netherlands, Belgium, Luxembourg, Germany, France, Switzerland, UK, Italy, Spain and Greece

and the Czech Republic, Poland, and Hungary. With a strong base in the Netherlands and Belgium, ING Europe plans to expand further. It sees European social security systems as weak due to increased costs and an ageing population which will provide new opportunities for insurance providers (ING Annual Report, 2001).

CIGNA

CIGNA International is part of CIGNA Corporation and offers life, health and employee benefits. Its main markets in Europe are in the UK and Spain. The health care insurance products cover government- approved medical benefits and offer an alternative or supplement to governmental programmes. Health care includes life and medical insurance products that are provided through group benefit programmes as well as medical insurance products marketed directly to individuals, including managed care. Supplementary insurance products cover accidental death, medical, hospitalisation and income protection. Health products are distributed through independent brokers and agents as well as CIGNA corporation outlets (CIGNA SEC report, 2001).

CIGNA's annual financial report (SEC, 2001) said "CIGNA intends to pursue international growth through acquisitions, joint ventures and other investments".

MEDICOVER

Medicover was established in 1995 by Oresa Ventures, a Swedish venture capital company. The company offers both medical insurance and a health care delivery system, to its clients. Medicover employs most of its physicians directly and provides health care through its own facilities. In 2001, it has 66,000 pre-paid members in Poland, 7,000 in Romania, 1,700 in Hungary and 300 in Estonia. It provides health insurance for corporations and individuals, health care services through 20 Health Centres staffed by its own doctors and nurses, and on-site workplace facilities for large employers.

Although originally a project supported by venture capital company Oresa Ventures, Medicover has become so successful that Oresa Ventures ceased to invest in new initiatives. ORESA Ventures' other holdings are being divested. As a result of the new focus, ORESA Ventures' name changed to Medicover and it become an operating healthcare company (www.oresaventures.com). It has received a loan of $7 million from the International Finance Corporation (out of a budget of $22million) (www.ifc.org)

CAPIO

Another example of Swedish financial investment in health care is Capio, floated as an independent company on the Swedish stock exchange in late 2000. Previously called Bure healthcare, it was owned by financial investment group Bure.

Capio AB's principal activity is the provision of healthcare services in Scandinavia and other European countries.
The Company operates through the following divisions:

- Healthcare services: hospitals, outpatient healthcare and psychiatry;
- Diagnostic services: provision of laboratory and radiology services;
- Elderly care services: care services for the elderly.

These are three significant areas in health care where private sector/ multinational providers are expanding.

Healthcare accounted for 73% of 2000 sales; diagnostic services, 19% and elderly care services, 8%. Capio Diagnostics is the leading radiology operator in the Nordic countries.

Capio is currently operating in Sweden, Norway, Denmark, the UK, Switzerland and Poland with an annual turnover rate of more than SEK 3,300 million. With the acquisition of the Community Hospitals Group in the UK (now Capio UK division), Capio's operations outside Sweden now generate more sales than operations within Sweden (Capio, Annual Report, 2001). Capio is also becoming a leader in the fields of laboratory medicine and ophthalmic care.

Customers are county councils, municipalities, businesses as well as public and private insurance companies that buy healthcare services. Capio's hospitals and other care units in Sweden are under contract to public authorities. Health care is provided on equal terms, with the same patient fees and priority rules as within public healthcare.

Annually, Capio carries out 2 million physician consultations, 8 million laboratory analyses and 500,000 X-rays.

Employees

The Capio Group comprises some 150 operating units with 10,000 employees, of which 2,000 are physicians.

Strategy/ market

Capio sees the public/private health care relationship as a significant factor in the future growth of the private health care sector. It has identified a growing role for the private sector in delivering services to the public health sector in Nordic countries and the UK. Capio is aware of some national differences e.g. between UK and Germany, in the different role of private health care sector and is ready to take up opportunities as they arise (Capio Annual Report, 2001).

Capio's recent acquisitions include: radiotherapy units in Norway and Finland, older people's homes/ facilities/ care in Sweden and the UK Community Hospitals Group.

FRESENIUS

Fresenius is an integrated kidney care company. It provides kidney dialysis equipment, products and services through four divisions: Fresenius Medical Care, Fresenius Kabi, Fresenius ProServe, and Fresenius HemoCare.

- **Fresenius Medical Care:** – products and services for individuals with chronic kidney failure, with some 1,300 dialysis clinics worldwide
- **Fresenius Kabi:** - a provider of products for nutrition and infusion therapy and outpatient medical care
- **Fresenius ProServe:-** management services as project development, consulting, and staff training to hospitals and other health facilities
- **Fresenius HemoCare**: focuses on blood treatment and infusion technology

Fresenius AG has operations in Asia, Europe, Latin America, and North America. North America and Europe are the main focus of sales with 57% and 32% respectively. South America and Asia-Pacific account for 5% and 6% of sales.

The company employed 49,974 staff in 2000 with 52% of the labour force in North America and 35% in Europe. 4,000 employees joined Fresenius in 2000 as the result of acquisitions. Fresenius Medicare (clinics) employs 71% of the labour force and has a 74% share of sales (Fresenius, Annual Report, 2001).

Strategy

Renal care is a growing area of healthcare and part of a very competitive market worldwide. There is growing evidence that companies which manufacture drugs and /or equipment for the treatment of kidney diseases are also involved in the provision of health care. Multinational companies involved in renal care have combined operations that include:

- healthcare – clinics for treating kidney disease
- renal products – products used during dialysis treatment
- blood compound technologies and blood bank technology –

This is an example of vertical integration of activities in the health care sector.

Merrill Lynch Global Fundamental Equity Research Department published a profile of the dialysis industry in September 2001 arguing that the production of dialysis products was no longer driving the industry because there is limited product growth possible as synthetic dialyses have become standard equipment (Kidney Machinations The Dialysis Industry could get bloody, Merrill Lynch Research Department, 11 September 2001). As a result, major companies will become service providers, for instance, running dialysis clinics, but may expand into other aspects of health care provision. Fresenius has already started to offer treatment for other aspects of patients' care. This will have implications for existing health care companies.

EUROMEDIC

Euromedic Diagnostics BV and International Dialysis Centre BV are both 100% owned Dutch subsidiaries of Euromedic International NV, a holding company of the group. Euromedic operates diagnostic imaging centres in Hungary and Poland and haemodialysis centres in Poland and Bosnia. In Hungary, it has 7 private diagnostic imaging centres seeing 20,000 patients per month. 100-150 staff, mainly doctors, are employed in Hungary. In Poland, Medicover has 3 diagnostic imaging centres and 3 haemodialysis centre seeing 2,500 patients per month. In Bosnia, it has one haemodialysis centre which sees 230 patients per month www.ifc.org).

Euromedic has also received a $13 million loan from the International Finance Corporation to fund a $33 million expansion programme in Central and Eastern Europe. Other shareholder include GE Equity – private equity arm of GE Capital, Dresdner Kleinwort Benson private equity fund, Global Environment Fund, RPM Partners, a Dutch private investment company and private investors led by Euromedic's management. One of the non-executive Directors of Euromedic (Janusz Heath) is the head of Central and Eastern European Private Equity Dresdner Kleinwert Benson.

QUEST DIAGNOSTICS

Quest Diagnostics is a laboratory testing business that provides diagnostic tests to patients, doctors and health care institutions through a network of laboratories. Quest provides routine tests – blood cholesterol, pap smears, HIV tests, pregnancy, alcohol and other substance-abuse tests. It also provides esoteric tests which cover less frequent tests cover endocrinology, genetics, immunology, microbiology, oncology. Quest Diagnostics manufactures diagnostic test kits for esoteric testing. The company also runs two clinical trials testing centres in the US and the UK as well working in partnership with two centres in Australia and South Africa (www.questdiagnostics.com).

Quest owns one of the largest privately owned clinical laboratories in the UK which was developed in partnership with an NHS trust/ hospital. In Mexico Quest owns three laboratories and provides testing services throughout Mexico. There is also a centre in Brazil and Quest is aiming to set up additional laboratory services in Brazil. Quest also provides esoteric testing services to the Nichols Institute, involved in clinical trials, which operate worldwide.

Quest Diagnostics employed 29,000 people in 2001, the majority in the United States.

Strategy
Quest took over SmithKline Beecham Clinical Laboratories, the laboratory business of SmithKline Beecham in 2000. In the past year it has acquired American Medical Laboratories, and Unilabs (California). It has also recently established an alliance with Roche Diagnostics to develop gene based medical testing (Quest Diagnotics SEC, 2001). Within the UK, Quest was involved in negotiations for a cross district laboratory centre in Manchester, in 2001, which although unsuccessful was indicative of interest in the new laboratory structures in the NHS (Health Service Journal, November 2001).

These recent acquisitions and alliances show the shared interests between the laboratory divisions of pharmaceutical companies and diagnostic testing businesses. The growing demand for esoteric tests, including gene testing, provides opportunities for expansion. These are expensive tests to provide requiring high technology equipment and staff.

ISS

International Service Systems ISS is a Danish company providing facilities services including cleaning, catering, and services for hospitals and older people's care homes. It works in a range of sectors and operates through the following divisions:

- Cleaning and maintenance - office cleaning for private and public sectors
- Services for the health sector - targeted at hospitals and other institutions within the health sector
- Services for the food industry
- Services for airports

Other business areas include: Canteen/catering services; energy/industrial high tech services; property services, care services and after-damage service.

International Service Systems ISS A/S currently has 259,739 employees worldwide (ISS Annual report, 2001).

Facility services represent 87% of sales in 2000/1. Hospital services contribute 14% of sales. Over 80% of hospital sales take place in Europe. ISS hospital services are distributed within Europe as follow: Germany 30%, UK 29%, Netherlands 6%, Central Europe 5%, Denmark 5%, Switzerland 5%, France 4%, Sweden 4%, Belgium 3%, Others 9%.

Strategy
Create 2005 is a new 5 year vision launched in November 2000. It develops service concepts from multi-services to facility services which is leading to integrated facility services. Separate business areas are being managed across country borders. The development of the facilities services package is most developed in the UK. Specialisation of cleaning concepts is most developed in Germany (www.issworld.com). ISS has also lost several contracts with the public sector in Denmark due to poor standards of delivery (Global Newswire 31 October 2001, 7 December 2001)

ISS has made a large number of acquisitions in the last few years. In the health sector, it has acquired a number of older people's facilities and medical facilities but in some cases it has also divested of recent acquisitions in the health care sector. The CarePartner division, which delivers medical facilities and older people's care in Denmark, Sweden, Norway and Finland (ISS Annual report, 2001), is being reviewed in 2002 which suggests that ISS's overall role in health care provision is still unclear.

SODEXHO

Sodexho is a French company which, like ISS, delivers services – cleaning, catering, to a range of sectors including the health care sector. It provides a range of services (often described as multi-service) to hospitals and to older people's care homes. These services may include, catering, cleaning, housekeeping, building maintenance and management of paramedical staff. Services delivered within the health care sector provide 18% of revenue (Sodexho Annual Report, 2001).

Sodexho has a total of 313,469 employees worldwide with 45% of employees in Europe.

In Europe, Sodexho has contracts with the health care sector in Belgium, Finland, France, Germany, Hungary, Italy, Luxembourg, Netherlands, Spain, Sweden, and the UK. It also has contracts with older people's care providers in Austria, Belgium, Finland, France, Germany, Italy, Luxembourg, Netherlands, Spain, Sweden, and UK (Sodexho Annual Report, 2001)

Strategy
Sodexho sees opportunities in global multi-site, multi-service contracts.
It is developing partnerships with public and private sector organisations in order to deliver services. In the health sector in the UK, Sodexho has been involved in several Private Finance Initiatives involving hospital building and management. It has recently been criticised strongly for poor standards of cleanliness at Glasgow Royal Infirmary (Daily Mail 26 January 2002).

CONCLUSION - Are health services national?

If this question is addressed in terms of European Union health / health care policy, the picture is a complex one. Subsidiarity has been an important principle for European health services but the impact of several EU Directives e.g. movement of professionals, insurance, is beginning to influence national health systems directly. Several rulings by the European Court of Justice have made national governments aware of the implications of greater consumer choice. If this is combined with the effect of increasing demand for health care services, often seen through increased waiting lists, then cross-border health care is likely to increase in the future. EU competition policy is also beginning to affect health care systems that have introduced business approaches and techniques and so can be less obviously defined as services of "general interest".

International insurance companies are developing strategies for increased expansion. Other companies providing services to the health care sector already have extensive activities in many European countries and are looking for opportunities to expand. As labour intensive industries, the number of workers employed by these companies is growing annually.

All the companies outlined above see European and other global opportunities for expansion in different aspects of the health care sector: insurance, clinical and diagnostic services, facility services and older people's care. Partnerships with the public sector are seen as an essential step towards developing and delivering new services and facilities.

The involvement of these companies in the delivery of health care services will have implications for health workers and for the accountability of public health systems. The need for a coherent EU health and health care policy, expressed through a new Treaty, becomes more urgent as the growing influence of EU directives and the activities of multinational companies within the health sector becomes more clearly understood.

Jane Lethbridge
PSIRU, 29 April 2002

APPENDIX A RECOMMENDATIONS

EU LEVEL

- Review existing health and health care policies together with ECJ rulings and publish in a new framework
- Work towards a new Treaty that includes health and health policy in the same way as social protection – integral to economic growth and development
- Strengthen the Health and Consumer Affairs DG to address wider health and health care policies across other Directorates

NATIONAL GOVERNMENT LEVEL

- Members states to adopt a more proactive approach to EU health and health care policy, recognising that subsidiarity is not viable for the future development of health care systems
- Member states should work together on:
    - Common problems of health care provision and financing
    - Defining a common set of aims and objectives for health care systems
    - Pricing of pharmaceutical and medical devices
    - Developing common agreements on voluntary medical insurance

- National governments to develop guidance for national health care institutions about the impact of EU competition law and ways of remaining providers of services of general interest
- New health care policies to address the impact of competition law
- National governments to provide more information for patients about treatment in other EU countries

TRADE UNIONS

- Monitor the impact of EU legislation and rulings on health care provision and health care institutions
- Lobby national governments about need for a new EU wide health policy and improved coordination of existing policies and rulings
- Recognise the threat to mutuality posed by insurance Directives and document recent challenges
- Raise awareness about the impact of EU competition law on health care institutions and ways in which health care institutions can remain providers of services of general interest
- Make EPSU/ ETUC a strong voice in this process}