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EU law and health policy in Europe

Julia Lear and Elias Mossialos

Although Member States retain the primary responsibility for organization and delivery of health services under Article 152 of the EC Treaty, this policy space is still shaped by Community law and policy. The Community did not have legal authority in the field of public health until 1999, when the public health article was amended and renumbered by the Treaty of Amsterdam as the current Article 152. Treaty Article 152 defines the role of the EU as complementing national policies, sets out procedures by which the EU institutions may act in the health field, and delineates the types of measures that may be enacted, but explicitly bars the use of harmonization. Thus, the EU is limited to establishing public health programmes and incentives for preferred health policies.

Although the EU has no formal legal powers to enact Community health care legislation, several different policy domains influence health policy, including principally: internal market, social affairs, public health, enterprise and economic policy. This diffusion of health care governance raises several complications. Without direct authority, there is no clear hierarchy for health policy decision-making. There are also the twin problems of accountability and transparency. Without a unified body of health legislation, independent bodies attempting to monitor, analyze, and report on the effectiveness of EU health policies must assemble a diverse body of legal documents and chase after a dispersed group of officials. Similarly, determining the scope of Europeans' rights to health care requires a search through the Treaty, the European Convention on Human Rights, the European

Social Charter, as well as a number of conventions governing everything from food safety to privacy to environmental protection. Since the European Court of Justice (ECJ) has not yet interpreted the legal weight of some of these laws, whether Europeans can legally enforce these rights remains an open question.

Without direct legislative authority, the European Commission has employed soft law mechanisms such as the Open Method of Coordination (OMC). In contrast to traditional legislative processes, soft law governance techniques are less hierarchical, more flexible, deliberative and consensus oriented. After the Treaty of Maastricht was adopted in 1993, expanding community authority to contribute "towards a high level of human health protection" (Article 129, now 152), the Council recommended that the Commission address the promotion of social Europe.¹ However, Member States had little political will to move health onto the European agenda. It was not until 2002 that the European Council of Ministers agreed that health care systems share common principles of solidarity, equity, and universality, but chose not to take any further concrete actions. After the health sector's exclusion from the EU Services Directive, which aims to break down barriers to cross-border trade in services between EU Member States, health and long-term care were formally added to Social OMC procedures conducted by the Social Protection Committee (SPC) in 2005. A wide variety of health related lobbying groups opposed the application of the Services Directive. The opposition argued

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that health care services are 'unique' and should not be treated as any other commercial service; and that Member States would have difficulty managing their health systems with the additional EU oversight. The 2008 Commission Communication on Social OMC proposes a new commitment to a social Europe that would strengthen the OMC process by setting targets, improving reporting, communication and dissemination as well as improving mainstreaming and horizontal coordination.²

One area where the EU does have explicit Treaty authority to legislate is in the area of public health. Within the public health sphere the EU has enacted legislation to ensure the quality and safety of blood, blood products and human tissues, and is considering legislative action to address the challenges of organ transplantation. The Community has also engaged in several strategies to detect and control communicable diseases. International health threats such as SARS encouraged the establishment of the European Centre for Disease Control (ECDC). The ECDC manages European disease surveillance and response systems*, identifies emerging health threats, provides scientific opinions, publishes epidemiological research, and trains scientists and researchers from all over Europe. The Community has also enacted legislation and public health campaigns to reduce the negative health impacts of hazardous products such as tobacco, alcohol, and illicit drugs. Another important area of EU public health policy is the establishment of regulatory agencies to provide expert opinions and advice, collect and disseminate information, and generally support Community Institutions. Health related agencies range from the European Monitoring Centre for Drugs and Drug Addiction to the European Agency for Safety and Health at Work. Two of the most important agencies are the European Medicines Agency and the European Food Safety Agency which play integral roles in the Community's

legislative authority to regulate the market authorization of pharmaceuticals, medical devices, and food (from 'farm to fork') to ensure that the products meet high levels of quality and safety for human consumption.

The establishment of the Single European Market also enshrined the fundamental freedom of movement of persons, capital, services and goods throughout the Community (See case study on cross border services). EU legislation on the free movement of professionals, including health professionals, has evolved through a series of directives leading to the current Directive on the recognition of professional qualifications.³ The aims of the directive are to ensure that Member States enact uniform, transparent, and non-discriminatory rules recognizing professional qualifications and experience to allow professionals to work temporarily or permanently throughout the Union. Despite efforts to harmonize procedures facilitating the free movement of professionals, Member States' regulations differ in the definition of scope of practice, requirements for knowledge and experience, and periodic re-validation. Although licensed professionals should not be discouraged from moving to a different Member State to work, some administrative and language barriers remain. However, the significant discrepancies in salaries across the EU will continue to motivate professionals to seek more lucrative positions when they can overcome the residual obstacles.

Other EU regulations, such as the Working Time Directive⁴ have had unintended negative consequences for the way health care systems function in Member States. While the Directive has the laudable aim of improving the health and safety of workers, it has created staffing problems for 24-hour health care facilities, especially in smaller communities. The directive defines minimum periods of daily and weekly rest, annual leave, and the maximum weekly working time. Although still not fully

implemented in the health sector, two ECJ cases have concluded that both 'on-call time' and 'stand-by time' are both considered working time for the calculation of maximum working times.⁵ Thus, implementation of the Directive in the health sector creates a number of scheduling problems and poses a threat to the survival of small hospitals serving dispersed populations.⁶ To ensure 24-hour year round coverage in a speciality, a rota must include up to ten doctors. This is far in excess of the number actually employed in some specialities, even in large hospitals. And although the number of hours worked decreases, the resulting shift patterns can be very disruptive for family life. Moreover, reduced working hours, coupled with the increasing use of out-patient care, significantly limit opportunities for doctors-in-training to have direct patient contact.

Finally, an area that has seen the most recent major developments is the free movement of patients. The Commission published in June 2008 the long awaited proposal for a directive on patients' rights in cross-border health care.⁷ The ECJ has developed most of the Community law in the area of patients' mobility. In 1998, the famous *Kobll and Decker cases*⁸ gave the Court its first opportunity to apply the free movement of persons provisions to the health sector. The Court found that Community nationals had the right to obtain medical treatment in any Member State without prior authorization and also to be reimbursed consistent with the tariffs of the state in which they are insured. Subsequent decisions clarified that a distinction must be made between hospital care and non-hospital care. Member States could adopt a system of prior authorization for planned hospital medical services obtained abroad, so long as the system is not arbitrary or discriminatory, is necessary and proportional, and its removal would not undermine the planning of hospital services.⁹ However, non-hospital care does not require prior authorization.¹⁰ Now the proposed new Directive goes further to define patients' rights to information and redress in the event of harm, as well as Member States' responsibilities:

* These include the European Influenza Surveillance Scheme (EISS), the Early Warning and Response System (EWRS) and implementation of the WHO 2005 International Health Regulation.

- to recognize prescriptions issued by an authorized person in another Member State (Article 15);
- to collect and transmit data on cross-border health services (Article 17);
- to facilitate the development and functioning of National Contact Points that will maintain information on everything from quality and safety, to the process for seeking redress and international out-of-court settlements (Article 12); and
- to cooperate with EU institutions and other Member States in the implementation of the directive (Article 13).

Whether the EU institutions will enact this legislation may not be known for several months. The negotiation process and its ultimate outcome will be significant indications as to whether the Community will encroach more directly on Member States' discretion to organize and provide health services, or whether health policy will remain dispersed in the grey zone of the EU's new governance.

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Public procurement and State aids in public health care systems

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Once it is established that health care services are 'services' within the meaning of the EC Treaty and that there is a 'market' for health care, public money cannot reach this market in an arbitrary way. Hence, public funds either have to be issued following a competitive tender based on objective and transparent criteria, or to be individually evaluated under the Treaty rules on state aids. This poses a set of fresh political and legal questions concerning the organization of public health care systems.

State aids and public procurement obligations under EU law

When public authorities wish to favour specific players in a given market, they can do so in two ways: directly, by giving them public subsidies, or indirectly by awarding them public contracts. Hence, both sets of EC rules are designed to prevent public authorities from unduly meddling in markets. The rules on state aids (Articles 87 et seq EC) prohibit such money injections unless they are specifically 'declared compatible' by the

Commission, following a notification procedure. The rules on public procurement, on the other hand, set out in Directives 2004/17/EC and 2004/18/EC (the Public Procurement Directives), require that public contracts are awarded following stringent requirements of (a) non-discrimination and equal treatment, (b) transparency, (c) proportionality and (d) mutual recognition. Contracts that are not covered by the Directives and do not have to comply with the Directive's technical rules are, nonetheless, subject to the same general

principles (the procurement principles).

A logical conclusion stems from the above. Since both sets of rules pursue the same objectives, they must not apply simultaneously, but alternatively. Indeed, one of the conditions for the application of the rules on state aids is that the recipient of the aid be an 'undertaking'. On the other hand, public procurement rules are deemed to apply to the so called 'public markets' (*marchés publics*), 'where the state and its organs enter in pursuit of public interest' and not for profit maximization. Therefore, it would seem that, to the extent that the two series of criteria are applied consistently, an entity which is not an *undertaking* will, more often than not, be considered to be a *contracting entity*. Hence, any given entity will be subject either to the competition and state aid rules or to the ones on public procurement – but not both.

This logical link has been turned into a formal one in the Court's judgments in *Ferring* and *Altmark*.¹ In these cases the Court held that, by virtue of Article 86(2) EC, subsidies given to an undertaking for the accomplishment of some service of general interest do not constitute state aids at all, provided that several conditions are met. These conditions make sure that compensation for the provision of public service is calculated according to clearly defined criteria, it does not cover structural inefficiencies of particular undertakings and that no overcompensation is allowed. All the *Altmark* conditions are clearly satisfied if the undertaking which receives public funds has been chosen through public tender according to the public procurement rules/principles. Therefore, the application of the procurement rules ousts that of the state aid rules.

The *Altmark* judgment has been followed by the so called '*Altmark* package'. This consists of three documents, one directive, one decision and one communication. Most relevant for the present purposes are the decision and the communication. Both describe in identical terms the conditions under which public service compensation should be given. The decision foresees that compensation given according to its rules to (a) any

small size service provider, (b) small and medium transport undertakings and (c) hospitals and social housing undertakings (without size limitations), is automatically lawful state aid and need not be notified to the Commission. The communication, on the other hand, sets a 'second best' solution for all other undertakings: they need to notify the aid received, but will be granted an individual exemption provided the 'compensation' complies with the communication's rules.

Effects of the EU rules for health care systems

In view of the great diversity characterizing the health care systems of the various Member States, it is impossible to determine in an all-encompassing manner the way in which the above rules may affect these systems. Some basic questions, however, will have to be addressed in all Member States, in order for their systems to cope with the EU rules.

A. Define public service in health care

The pursuance of public service is a key criterion for qualifying a body as a 'contracting entity' in the sense of the Public Procurement Directives. At the same time, it is the main condition for the application of the 'compensation' logic inaugurated with the Court's judgment in *Altmark*. If the personal scope of public service is defined in an inelastic manner by the objective of universal coverage, there remain at least three variables in defining its scope in the field of health care: (a) the kinds of treatments (and pharmaceuticals) covered; (b) the level of quality of medical services (qualification and number of health professionals, level and quality of infrastructure, conditions for access to the system, waiting lists etc); and (c) the quality of non-medical services (accommodation, catering, cleaning etc). Therefore, it would seem that the application of EC law would require the introduction, in the field of health care, of the concept of 'service of general interest' or 'public service' and a precise definition of its content. This, in turn,

entails a logical shift: while the national logic is one of defining the scope of a health care system, the EC logic is to define a set of health care services of general interest.

B. Financing the cost of public service in health care

According to the *Altmark* criteria, overcompensation is not allowed, while only costs directly stemming from the performance of public service may be compensated for. This means that hospitals and other health entities need to clearly distinguish capital from exploitation costs, ie. costs directly linked to the volume of services provided. Furthermore, if the cost of the public health service is to be determined in advance, the use of DRGs* or equivalent measuring units is crucial. Finally, Member States should put into place a system of monitoring hospitals etc, in order to make sure that (a) they properly accomplish the public service tasks entrusted to them and (b) in doing so, they receive no overcompensation.

C. Undertakings vs contracting entities: criteria for qualification

In the analysis above it is argued that any given entity should qualify either as a 'contracting entity' or as an 'undertaking' and that the two qualifications should be mutually exclusive. This, however, is not necessarily true in a hybrid economic sector, such as the provision of health care.

In the case law of the European Court of Justice several criteria are proposed in order to legally qualify the various entities involved in the provision of health care (insurance funds, hospitals, ambulance services, health professionals etc). These criteria, however, are not used by the Court in any consistent manner and are often contradicted by national courts and competition authorities, and even by some EC texts. In this respect, Decision 2005/842/EC (the *Altmark* decision) is a positive step, since it clears hospitals, irrespective of their qualifica-

* Diagnoses Related Groups: pre-defined pairs, whereby each specific medical condition is matched up with a determined treatment and/or length-of-stay.

tion as undertakings, from the application of the state aids rules. However, legal uncertainty is deemed to persist in this field, especially in view of the diversification of health care provision in the various Member States.

D. What award procedures should be followed in the field of health care?

Even where a 'contracting entity' is active in the field of health care, it is never fully bound by the public procurement rules. Four cases may be distinguished: (a) for 'in-house provision', where the entity itself (or together with other public entities) provides the services, there is no contractual relation and the procurement rules are not applicable at all; (b) the same is true in cases where the State enters into contracts with *anybody* who fulfils some pre-set conditions; (c) only the procurement *principles* (as opposed to rules) apply in the case where the State confers some exclusive right to a given entity; and finally (d) even where a proper competitive tender is to be held, according to the Public Procurement Directive (2004/18/EC), in relation to health care services only minimal legal requirements apply: the use of objective technical specifications and the publication of a post-award notice.

In view of the above it becomes clear that as long as the EU lacks the political will – and the competence – to put forward measures of positive integration (harmonization) in the field of health care provision, the application of the general (negative integration) rules (i.e. the general Treaty rules prohibiting discriminations against and restrictions to free movement) will continue to produce further diversity, at least in the short term.

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Competition law and health services

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The European Court of Justice's (ECJ) application of EU internal market rules to the health sector has expanded the influence of the European Community into health policy. Specifically, enforcement of EC competition law by the ECJ and national courts has ensured that health care providers and insurers follow Single European Market rules if they compete in the health market as 'undertakings' similar to companies competing in other markets. National health policy makers who do not follow EU legal developments may make the assumption that since health care provision has traditionally not been subject to EU laws, they may continue to define and implement health policy free from worry about EU regulation. However, Community competition rules prohibit undertakings from participating in anticompetitive activities such as agreements to set prices or abuse of dominant position, under Treaty Articles 81 and 82. Health policy makers ignore these rules at the peril of having their policies challenged in court.

These issues raise several questions: What are undertakings? How do they participate in national health systems? What are the rules limiting their activities? How have the rules been applied in the health sector? Finally, what options do Member States have to protect national health policies from the long reach of the EU?

The term 'undertakings' is not defined within the EU Treaty, but by a series of ECJ cases. The concept focuses on whether the entity participates in the market, not who owns it or whether it has non-profit status. Undertakings are classified by engaging in economic activities, in contrast to public service organizations engaged social activities based on solidarity.¹ For example,

German sickness funds are not considered to be undertakings since they are based on the solidarity principle and are regulated by statute to provide defined benefits at set contribution rates.² As European governments introduce market reforms hoping to make health systems more efficient, the payer and provider functions have been separated requiring contractual arrangements, which are also more consistent with internal market rules. Once organizations such as insurance funds or hospitals compete for private paying customers, and solidarity principles no longer guide their primary function, competition rules may apply. Although this binary dichotomy may sound clear in theory, it is controversial in practice. Consider the complexity of public private partnerships. In Austria, Germany, and several of the newer Member States reforms have transferred publicly-owned hospitals to private management. Depending on the level of independent discretion to generate revenue and provide services, these organizations may fall into the category of undertakings and could trigger the application of competition law.

Once a court has determined that competition rules apply, the undertaking's activities are governed by extensive rules to protect the internal market's neutral playing field. Article 81(1) prohibits undertakings from practices 'which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market.' Article 81 further precludes undertakings from forming cartels that interfere with competition by making agreements to fix prices, limit sources of supply or other anti-competitive behaviour. National courts and National Competition

Authorities in several Member States have sanctioned professional associations as anti-competitive cartels for engaging in unlawful price fixing agreements. As early as 1992, the Finnish Competition Council found that the Finnish Medical Association and Dental Association violated the price cartel prohibition by recommending prices to members.³ Similarly, the Czech, Greek, Hungarian, Italian and Portuguese competition authorities each fined professional health associations for anti-competitive fee setting practices.⁴ Undertakings must also refrain from abusing a dominant market position with practices such as discouraging competitors from entering the market, selective contracting, or predatory pricing, under Article 82. The UK Office of Fair Trading awarded damages to Healthcare at Home, an in-home-care provider, against another provider Genzyme, for abuse of dominant position in bundling the price of its services to include the cost of providing home delivery.⁵

National Competition Authorities (NCA) in several Member States also play an advisory role, commenting on proposals, enacting health legislation or conducting health sector analysis to determine areas where competition may be improved. The Finnish NCA supported legislative reforms requiring generic substitution of medicines and proposed additional amendments to enhance financial incentives.⁶ In Sweden the NCA published a market analysis which found that the tight regulation over the establishment of new local medical practices has resulted in a decline in the number of new doctors entering private practice, limiting health services supply.⁷

To protect health systems from the restrictions of competition law, European health policy makers have two primary options, and both have their flaws. First, they may maintain vertically integrated public systems free from private funding, financing, and service provision. Alternatively, they could identify specific health services as a 'service of general economic interest' (SGEI) under Treaty Articles 16 and 86(2). SGEI is an exemp-

tion from competition law that has been raised by Member States as a defence when their market-correcting policies are challenged in court. For example, in 2001 the ECJ upheld a state grant of exclusive rights in Germany to provide ambulance services in a rural area, as being necessary to ensure the economic viability and reliability of emergency transport.⁸ More recently, the Irish risk equalization scheme applied to the country's health insurance funds was upheld as a SGEI, since the scheme is designed to provide all Irish residents with access to a minimum level of private health insurance services at the same price.⁹ However, government policies relying on the SGEI exemption are not without risk, since the defence would be raised after the policy has been challenged in court and presumably already implemented. Moreover, the Court limits anti-competitive policies under SGEI to what is necessary and proportionate to achieve the market-correcting public service. This analysis is only conducted on a case-by-case basis and leaves policy makers with no clear rules for guidance. Therefore, European health policy makers should consider the restrictions of EU economic regulation when designing and implementing health services.

Despite the EU's lack of explicit competence in the area of health, Member States' domestic health care systems do not enjoy immunity from the application of EU competition law. Even incremental reforms to improve efficiency based on market competition may open the door for competition laws to apply. There are few bright distinctions between economic and social functions in mixed public and private health systems. Although competition law will not necessarily apply, the services of general interest exception will not always provide a safe harbour allowing Member States to distort or restrict competition when regulating health services. Currently, it is

difficult to predict the impact of future court cases on health systems. The only thing that is clear is that health policies should continue to be analysed within the framework of EU competition law.

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Internal market rules and regulation of private health insurance: threat or opportunity?

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European Union (EU) internal market rules affect the regulation of private health insurance through the Third Non-Life Insurance Directive introduced in 1994 and most recently amended in 2007.¹ To facilitate the free movement of services, the Directive outlaws insurance monopolies, requires equal treatment of insurers (regardless of profit status) and generally prohibits ‘material’ regulation in the form of price and product controls. The Directive does not apply to health insurance that forms part of a country’s social security system; but all other forms of health insurance, which we refer to as ‘private health insurance’, fall within the Directive’s scope. With its prohibition of material regulation, the Directive has the potential to restrict a government’s freedom to regulate a market that is known to suffer from various failures.² This might threaten consumer protection and affect access to health care for some groups of people. However, if policy makers are genuinely concerned about access to health care, one strategy might be to make sure that statutory health coverage is universal, falls squarely within the boundaries of ‘social security’

and covers a wide range of services, thus eliminating or lowering the need for private health insurance.

Do EU internal market and competition rules present policy makers with a threat or an opportunity? To answer this question we need to look at the impact the Directive has had on regulation of private health insurance, as well as the different roles private health insurance plays across the EU. When the Directive was introduced, countries varied widely in the way in which they regulated private health insurance.³ The extent to which governments intervened in markets for health insurance largely depended on the role private cover played in the health system (Table 1). For example, in Germany and the Netherlands, private health insurance substituted for statutory health insurance for higher-earning households. The government therefore intervened quite extensively in the market to protect older and less wealthy households (and the finances of the statutory health insurance scheme, which covered a disproportionate amount of higher-risk households) from the effects of risk selection by private

insurers. Elsewhere, the extent of regulation was influenced by political ideology as well as aspects of market structure, such as the number and mix of insurers in operation. Market structure was particularly influential in markets dominated by mutual associations, where policy makers often used fiscal policy to favour mutuals over commercial insurers. In most countries, the main method used to protect consumers (in addition to solvency controls) was prior approval of policy conditions and premium rates. Ireland was the only country that restricted the sale of private health insurance to a single quasi-governmental insurer (Vhi Healthcare, then known as the VHI Board).

Following the introduction of the Directive, most member states amended existing laws or passed new laws to comply with it. Legislative changes generally involved the introduction of tighter solvency controls and the abolition of prior approval or systematic notification of policy conditions and premium rates. France proved to be the exception in this respect, and the European Court of Justice (ECJ) ruled against the French

Table 1 Classification of private health insurance markets in the European Union

Market role	Driver of market development	Nature of cover	EU examples
Substitutive	Public system inclusiveness (the proportion of the population to which coverage is extended)	Covers population groups excluded from or allowed to opt out of the public system	Germany, the Netherlands (prior to 2006)
Complementary (services)	Scope of benefits covered by the public system	Covers services excluded from the public system	Belgium
Complementary (user charges)	Depth of public coverage (the proportion of the benefit cost met by the public system)	Covers statutory user charges imposed in the public system	France, Slovenia
Supplementary	Consumer satisfaction (perceptions about the quality of publicly-financed care)	Covers faster access and enhanced consumer choice	Ireland, United Kingdom

Source: adapted from Mossialos E and Thomson S, 2002⁴ and Foubister T, Thomson S, Mossialos E and McGuire A, 2006⁵

government in May 2000.⁶ The biggest change took place in Ireland, where the government was forced to open its market to competition and established a stringent regulatory framework involving open enrolment, community rating of premiums and a risk equalization scheme. With the exception of risk equalization, which was introduced to prevent cream skimming in a competitive environment, the other regulations had already applied to the VHI Board prior to 1994 and were not new. What was new, however, was that the role played by private health insurance in Ireland had changed. Whereas prior to 1991 private health insurance had played a substitutive role, providing access to hospitals for people who were not eligible for free inpatient care under the statutory health system, by 1994 its role was partly complementary (reimbursing statutory user charges for outpatient care for richer households) and largely supplementary (giving policy holders faster access to elective care provided in private hospitals or private beds in public hospitals).

Article 54 of the Directive includes specific rules for health insurance that constitutes a 'complete or partial alternative' to statutory health insurance provided by social security systems. In such cases, the Directive permits governments to impose material regulation in the interest of the general good. Examples of permissible measures include open enrolment, community rating, standardized benefits packages and risk equalization schemes. However, there is uncertainty in interpreting what the Directive means by 'complete or partial alternative'. There is also uncertainty regarding the type of intervention that might be permissible. In 2003 BUPA Ireland, the main rival to Vhi Healthcare in the Irish market, seized on this uncertainty to challenge the Irish regulatory framework at the European Court of Justice (ECJ). BUPA argued that the risk equalization scheme was a form of state aid to Vhi Healthcare, which had an older age profile and would therefore be a net beneficiary of the scheme. It also argued that the broader regulatory framework might contravene the Directive and could not be justified under general good principles since

private health insurance in Ireland did not constitute a service of general economic interest (SGEI) or a complete or partial alternative to statutory health insurance.

In 2008 the Court dismissed BUPA's arguments.⁷ It found that private health insurance was, in fact, a service of general economic interest, mainly because the Irish government considered it to be so, but also because the framework for regulating private health insurance strengthened the government's case in this respect. It further noted that the Irish government considered private health insurance to be the second pillar of the Irish health system and that the Court had no power to question this view, although in its opinion the fact that the market covered about half of the Irish population gave credence to the government's view. The Court's decision suggests that EU law gives governments considerable leeway to justify regulation of private health insurance as serving the general good (that is, as being in the public interest), and that any justification will be bolstered by the fact that private health insurance covers a significant proportion of the population.

The BUPA ruling is an interesting development, since it comes a year or so after the European Commission began infringement proceedings against Slovenia and Belgium on the grounds that differential treatment of insurers (Belgium) and material regulation, including a risk equalization scheme (Slovenia), contravene the Directive. In the Slovenian case, the Commission does not consider the complementary private health insurance market, which covers the costs of statutory user charges, to provide a complete or partial alternative to the statutory health insurance scheme. However, given that the market in Slovenia is considered by the government to be a 'second pillar' of the health system and covers about 70% of the population, following BUPA the Commission's interpretation seems open to challenge. The Belgian case may be more straightforward, since ECJ rulings have generally confirmed that it is difficult for governments to justify fiscal or other forms of differential treatment of insurers.

Part of the Directive's logic in allowing material regulation in private health insurance markets that form an alternative to statutory cover seems to be to permit governments to ensure access to markets that contribute to financial protection (social protection in EU terminology). Substitutive markets clearly fulfil this remit and the Commission and others have not challenged the extensive regulations in place in Germany or in the Netherlands. We argue that complementary markets may also contribute to social protection, particularly where they cover statutory user charges, as in France or Slovenia. If the Directive prevents governments from ensuring access to this form of complementary cover, it may undermine social protection. Having said that, the BUPA case suggests that the Directive may become increasingly irrelevant in the light of developments in EU policy on services of general economic interest. What happens in the Slovenian case will shed further light on this line of thought.

As we have suggested, the Directive ought, perhaps, to discourage policy makers concerned with ensuring access to a high degree of social protection from relying on private health insurance to complement – or even substitute for – statutory cover. Currently, the Commission has confirmed that the new system of using private insurers to offer statutory health insurance in the Netherlands falls within the scope of the Directive, and it has given the go ahead to the Dutch risk equalization scheme. Nevertheless, its decision is being challenged at the ECJ by a private insurance company. Due to the precedent set by the BUPA case, the Court seems unlikely to rule against the Dutch regulations. But the existence of the legal challenge illustrates how increased blurring of the boundaries between normal economic activity and social security can give rise to complexities that the Directive does not seem equipped to address. In light of these complexities, it is probably time for a debate about how best to move forward. A priority for debate should be to find ways of thinking about private health insurance that go beyond 'partial or complete alternative' to statutory cover. These terms do not sufficiently

reflect the often complicated relationship between public and private cover. And, at least in the European Union, private health insurance rarely offers a genuine 'alternative' to statutory cover.

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An expanding toolkit for the European pharmaceutical market?

Leigh Hancher

The European pharmaceutical market is traditionally characterized by competition between new, patented, innovative products (often referred to as therapeutic competition) and from generic products as well as parallel imports.* Recent developments suggest that the European Commission has considered it necessary to expand its 'tool kit', to include stricter ex post controls on certain practices by the research-based industry to frustrate its generic competitors. In this context, the application of Article 82 EC (which prohibits the abuse of a dominant position) is now becoming of greater significance.

Parallel imports

Although the Commission has generally had a positive view of parallel imports as a way of cementing the internal market in pharmaceuticals, the recent reappraisal by European as well as national courts of dual pricing strategies, whereby research-based manufacturers seek to prevent parallel trade, suggests that parallel trade may not be protected in the future. Recent case law indicates, albeit cautiously, that this type of preventive strategy may be pursued under certain conditions, perhaps undermining the Commission's stance on parallel imports. For example, in its ruling in the GlaxoSmith Kline (GSK) case, the Court of First Instance (CFI) rejected the Commission's argument that GSK's policy had the object of restricting competition.¹ It held that the

Commission should have fully examined the entire regulatory and economic context. Appeals to the ECJ have been lodged against the CFI ruling.

Generic medicines

Generic competition is encouraged at European and national level,** but at the same time the research-based industry is protected from generic competition by a number of legal and regulatory instruments which aim to encourage R&D by granting innovative products a de facto market exclusivity, at least for a specified period of time. As a result of recent amendments to the European product licensing regime, a new term 'market exclusivity' has been introduced to prevent the marketing of a generic drug during the two years following the expiry of the data exclusivity period – increasing the overall period of time that generic manufacturers must wait before registering their products. In addition, generic manufacturers claim that the registration and use of generic medicines is hampered due to a lack of EU-wide harmonization of indications of reference products (also known as 'originators') on which the generic applicant must base its common European-wide approval. This is, in part, attributed to the extension of the types of properties eligible for intellectual property rights protection (IPR) in general, through the combination of patent, trademark and copyright.²

* Parallel imports relate to the purchase of medicines by a wholesaler at low prices in one country and their subsequent import and resale at higher prices in another country. As different European governments have different pricing regulation policies, variable prices for a product can exist across the EU.

** In its Communication of 1 July 2003, the Commission confirmed that "generic medicines can provide significant savings to healthcare providers. However, their use must be balanced with sufficient incentives to develop innovative products."

Competition law and IPRs

In May 2006 the Commission imposed a fine of €60 million on Astra Zeneca (AZ) for abusing its dominant position by delaying generic market entry of generic copies of its best-selling product, Losec (a proton-pump inhibitor).³ AZ developed a central strategy to protect Losec's market position in Europe after expiry of the basic patent on the active ingredient by seeking to obtain additional patent protection in a number of different countries. AZ's 'misleading representations' to the patent authorities were held to be abusive since they were part of a centralized strategy to prevent generic market entry. The Commission also condemned AZ's strategy of selectively withdrawing the market authorization of Losec in favour of an improved version in the countries where, due to the specific market situation, generic competitors, as well as parallel importers, would have been able to launch generic copies unless the 'reference product' was made unavailable. Subsequent regulatory changes should make it impossible to repeat this type of conduct.

The Astra Zeneca decision is the first time that the Commission has relied on Article 82 to penalise conduct before national patent offices and regulatory authorities responsible for marketing authorizations. Importantly, the Commission drew a distinction between marketing authorizations, which unlike patents and data exclusivity, are not intended to reward innovation, but instead merely give the right to sell products on the market. The decision is under appeal, but in the meantime the Commission has launched similar investigations into alleged abusive conduct by other companies.⁴

The Commission Inquiry

The Commissioner for Competition has now publicly acknowledged that 'generic competition is an area which has suffered from under-enforcement in the past', and has taken action accordingly. The launch of the Commission's sector-wide inquiry on 16 January 2008, unusually, was heralded by dawn raids at the offices of at least eight major pharmaceutical

companies. The inquiry will focus on two particular issues: agreements between pharmaceutical companies, such as settlements in patent disputes, and to establish whether companies have created artificial barriers to product entry, through misuse of patent rights, vexatious litigation or other means. The launching of the inquiry signals the Commission's willingness to get to grips with the impact of competition on the patent strategies of the manufacturers, particularly towards the end of a product's patent life. However, in the final event, the actual effectiveness of this new addition to the Commission's tool kit will depend on the follow-up steps taken on completion of the Commission's final report – scheduled for spring 2009.

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Cross-border services

Rita Baeten

The right of patients to freely seek health care in the EU and that of health professionals to establish themselves in another EU country has never been contested. The EC Treaty even explicitly mentions the freedom of establishment of medical professionals and subjects this freedom to a specific legal framework.¹ The consequent directives set out rules on EU-wide recognition of health professionals' qualifications, ensuring access to the exercise of a medical profession.²

Notwithstanding this, for a long time it was generally assumed that the EC provisions on free movement did not apply to statutorily covered health care services. It was considered that their integration in publicly-funded systems, that aimed to guarantee universal access, sheltered them from the application of the internal market rules. However, since the end of the 1990s the European Court of Justice (ECJ) has made it clear that health care provision, irrespective of the way it is funded, is an economic activity and thus has to comply with the EC Treaty rules on the freedom to provide cross-border

services and the freedom of establishment.³ As part of the single market, these freedoms aim to boost the EU economy by removing obstacles to trade between Member States. The freedom of establishment guarantees the ability of care providers to establish themselves in a stable and continuous way in one or more Member States. The freedom to provide services, on the other hand, guarantees for providers, once established in a Member State, the freedom to supply (on a temporary basis) services in other Member States without having to establish in the Member State of service provision. This freedom also includes the freedom to provide cross-border services at a distance, e.g. through the internet, and the freedom for the recipient of a service to go to the Member State of the service provider without being obstructed by restrictions.

The Court thus has made clear that requiring prior authorization from a patient's national social security system before refunding the expenses of planned medical treatment sought abroad is a

barrier to these free movement principles. According to the ECJ, while this obstacle could possibly be justified for hospital care, it cannot for ambulatory care. The consequent policy process has sought to find an answer to the legal uncertainty for patients, providers and health authorities regarding the rules applicable to the reimbursement of care received abroad, finally culminating in the 2008 Commission proposal for a Directive on the application of patients' rights in cross-border health care.⁴

Yet, gradually it has become clear that the implications of these rulings go far beyond the issues related to patient mobility. Not only do the rules on reimbursement of care for patients going abroad potentially form an obstacle to free movement, but other regulations limiting access to health care services or restricting exercise of these activities can also form a barrier to the single market. This became particularly clear with the much debated Directive on services in the internal market, the so called Bolkenstein Directive, launched by the European Commission in 2004. The initial proposal applied to health care as well as all other services. It would have obliged Member States to assess whether their health care regulation (e.g. planning of health care services and tariff setting) was necessary and proportionate and if not, to make the necessary changes. However, health care was finally withdrawn from the scope of this directive in 2006.⁵

The provisions in the initial proposal of the services Directive should not have come as a complete surprise, however. Indeed, whereas the free movement rules initially aimed to guarantee that service providers established in a Member State would enjoy the same conditions as the nationals of the state in which they operate, the interpretation by the ECJ of what constitutes a barrier to free movement has gradually extended to measures that are applicable, without distinction, to domestic and foreign operators alike but which hinder or render less attractive the exercise of these "fundamental freedoms". The threshold for the application of the free movement rules on health services thus has become relatively low and health care providers can challenge regulation

not only if they consider it to potentially hinder their free movement, but they may even challenge the very existence of the regulatory measure itself.³

However, the application of free movement rules in the field of health care is not unconditional. The Court is aware that important market failures could occur when health care is delivered in an unregulated setting. For instance, it has recognized the protection of public health and the sustainability of health care systems as public interest objectives which can justify obstacles to free movement. In this respect, three conditions apply: (a) it must be proven that the measure is necessary to protect the public interest objective; (b) that it does not exceed what is necessary to attain this objective; and (c) that the result cannot be achieved by a less restrictive measure. As a consequence, health authorities face a relatively high burden of proof. Regulatory bodies are required to demonstrate that general measures also are justified in the specific situation of individual providers (or patients) and they have to provide evidence showing that the non-application of a restrictive measure in a particular case would jeopardize the public interest objective.³

Actors have only gradually become aware of what is at stake. Health authorities are concerned that they might lose steering capacity of the health care system and fear that legal uncertainty might lead to creeping deregulation. However, it is proving to be extremely difficult to find adequate policy responses to the developments. The complexity of the issues at stake and the lack of a clear legal basis in the Treaty play an important role. Moreover, a legislative initiative would inevitably imply making more explicit the conditions under which regulatory measures are considered compatible or incompatible with the free movement provisions. Thus, Member States seem to be caught in the paradox that in order to safeguard their national autonomy they have to accept some EU interference in their national health policies. The European Commission (where the different relevant DG's have diverging views on the issue since they have different objectives and different responsibilities) also seems unable to

provide more clarity. Its recent proposal on patients' rights in cross-border health care carefully avoids addressing these issues.

As a result, regulation in the health care sector will increasingly be scrutinized as to its compatibility with the free movement provisions. The long term effects of these developments remain rather unpredictable. They could create more diversity in health care provision and more fragmented health care systems. Moreover, increased choice for patients and providers might challenge public support for the equity and solidarity principles underpinning many European health care systems. If these effects are not intended, political action seems desirable.

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FORTHCOMING STUDY

Health Systems Governance in Europe: the role of EU law and policy

Edited by

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Commentators increasingly have highlighted that there is a dissonance in the European approach to health policy. Within the European Union, the Treaties stipulate healthcare as an area of exclusive Member State authority, but issues pertaining to healthcare financing, delivery and provision are affected by other elements of EU policy, particularly via the Single European Market. These impacts have resulted in a growing role for the European Court of Justice in setting precedents, and in turn, have fed into a tension with the social solidarity values that underpin many national healthcare systems.

What and where are these impacts? What are the emergent tensions? And what are the results for national policy-makers in Europe and their responses? These are among the questions addressed in this volume. In analysing key thematic and sector issues, and drawing on policy and legal expertise, the book provides not only a comprehensive and topical overview, but a multidisciplinary analysis of developments related to EU law and policies that have an impact on national healthcare systems within Europe.

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