

The influence of EU law on the social character of health care systems in the European Union

Executive Summary

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Elias Mossialos

Co-Director, LSE Health and Social Care, London School of Economics and Political Science and Research Director,
European Observatory on Health Care Systems

Martin McKee

Professor of European Public Health, London School of Hygiene and Tropical Medicine and Research Director,
European Observatory on Health Care Systems

Willy Palm

Director, Association Internationale de la Mutualité, Brussels, Belgium

Beatrix Karl

Assistant Professor, Institute for Labour Law and Social Law of the Karl-Franzens-University Graz, Austria and
Visiting Fellow, Max-Planck-Institute for Foreign and International Social Law, Munich, Germany

Franz Marhold

Professor, Institute of Labour Law and Social Security Law, Karl-Franzens-University, Graz, Austria

EXECUTIVE SUMMARY

Although Member States vary considerably in the detail of how they organise their health care systems, underlying all of them is a common model based on social solidarity and universal coverage. The precise nature of entitlement varies.

In countries with a single national health system funded from taxation, entitlement is usually straightforward, based on residence within the country in question. In social insurance systems the situation is more complex, especially where there are multiple funds, but membership is always compulsory, except in the few countries that have exempted or excluded the wealthier parts of the population on the assumption that they can make alternative arrangements. Even in these cases, governments may require cover against catastrophic illness, as in The Netherlands. More recently; arrangements have been introduced for those who would otherwise not be covered, although it must be recognised that these may still exclude certain groups such as illegal migrants.

However the European social model goes beyond simple coverage, seeing social protection as a means of promoting both social cohesion and economic growth. To achieve these goals requires that health systems be organised in ways that deliver equitable access to effective care. Health systems should do more than simply meet expressed demand by individuals. Specifically they should actively assess the health needs of their populations, in particular those that are not being met, and ensure that effective policies are provided equitably to meet them. The extent to which this approach has been implemented does vary but it is a clearly identifiable aspiration in all EU health care systems.

Essentially, the European social model is based on the premise that health care is not a normally traded good and access to it is a fundamental right. Consequently, it is based on a complex system of cross-subsidies, from rich to poor, from well to ill, from young to old, from single people to families and from workers to the non-active. This model has continued to attract overwhelming popular support, reflecting the historical forces from which it emerged and the deeply rooted values of solidarity in Europe.

A market for health care delivery is inevitably imperfect; individuals may not always be in the best position to assess their health needs, whether because they are unaware of the nature of their health need or are simply unable to voice it effectively. Health care is increasingly complex, creating major information asymmetries that open up scope for exploitative opportunistic behaviour by providers and thus a need for effective systems of regulation and oversight. For these reasons, all industrialised countries have taken an active role in the organisation of health care. Even the USA, which stands apart from every other industrialised country in its misguided belief in the applicability of the market in health care, has established a substantial public sector, covering about 40% of the population to address at least some of the more obvious symptoms of market failure. As a consequence, Member States have explicitly stated, in the Treaties, that the organisation and delivery of health services and medical care remains a matter of national competence.

Nevertheless, many individual elements of health care are, entirely reasonably, subject to market principles. Governments generally do not produce or distribute pharmaceuticals. Health facilities purchase equipment, whether clinical or otherwise, on the free market. Both medical equipment and technology are freely traded on the international market. Many health professionals are self-employed, engaging in contracts with health authorities or funds. Patients may obtain treatment outside the statutory health care system, either in their own country or abroad. All of these matters are entirely legitimate subjects for applications of the internal market; indeed the

fundamental freedoms enshrined in the Treaty require that such transactions are transparent and non-discriminatory. Furthermore, to the extent that reforms of health systems adopt market mechanisms, they indirectly become exposed to the scrutiny of European law.

This situation creates certain difficulties. Policies developed to sustain the principle of solidarity, with its complex system of cross-subsidies, are especially vulnerable to policies whose roots are in market principles. Unregulated competition in health care will, almost inevitably, reduce equity because of the incentive to select those whose health needs are least, making it difficult or expensive for those in greatest need to obtain cover. Risk adjustment systems can be established but are far from perfect, especially in an intensely competitive environment. Cost containment policies may be based on restricting supply, such as the number of health facilities. This may be undermined if patients can require their funders to pay for treatment elsewhere. Policies that address the issue of information asymmetry may involve selective contracting with providers but this requires the existence of agreed uniform standards. Concerns about information asymmetry have also caused European governments to reject policies that may seem, superficially, to redress this asymmetry, such as direct to consumer advertising of pharmaceuticals, on the basis of empirical evidence that it is often misleading and drives up health care costs while bringing few if any benefits to patients. However this is clearly an interference with the working of the market. In other words, even for those elements of health care that are covered by internal market provisions, Member States and the European Union have stated explicitly that the effects of the market must be constrained.

At present, therefore, health and social policy in Europe is being developed in an extremely disconnected fashion. Member States decide the goals they wish to pursue, such as equity and more effective care, and must then find mechanisms by which to do this that are consistent with European law. Much of the relevant European law has emerged from rulings that have either arisen from considerations in other sectors or, by addressing only the issues in a single case, leave major issues of applicability unresolved. As a consequence, health policy makers are confronted with a mass of contradictory advice from those who take either a restricted or expansive view of the scope of European law in health care.

The evolving issue of free movement of patients is instructive. The Kohll and Decker rulings of the European Court of Justice (ECJ) forced the Luxembourg social security system to reimburse unauthorised health care in another Member State on the basis of the Community principles of free movement of services and goods. This made it clear that social security systems, even if a matter of national competence, were not exempt from European law. Following from the later cases of Smits and Peerbooms, the ECJ clarified that all medical services, including hospital treatment, fall within the definition of services according to the EC Treaty, since in one way or another the provider is remunerated for the delivered service. The fact that reimbursement was claimed under the Dutch health insurance system, which operates through a benefits in-kind approach, was not considered relevant.

Even if the ECJ considered that requiring prior authorisation in all cases in which health care is delivered in another Member State constitutes a barrier to free movement of services and goods, it accepted in the Smits-Peerbooms cases that it was a necessary and reasonable measure to guarantee a balanced and accessible supply of hospital services. However, the Court would only accept such an exemption to the principle of free movement of services if the criteria applied to grant the authorisation were objective and non-discriminatory vis-à-vis providers established in another Member State. In that respect, it found the Dutch authorisation conditions not to be compatible with the principle of equal treatment, because they are likely to favour Dutch providers.

While not completely outlawing the use of a prior authorisation system, the Court rulings have radically restricted Member States' discretion to determine their own policies by requiring that their decisions are necessary, proportional and based on objective and non-discriminatory criteria. Furthermore, in the Vanbraekel ruling, the ECJ considered that if authorisation is given – or is wrongly refused – the patient should be granted the best possible reimbursement tariff, either that of the home country or that of the providing state. By linking the Regulation 1408/71, on which cover for health care abroad has been traditionally based, with the free provision of services, the ECJ seems to have created difficulties for this system of co-ordination system.

The jurisprudence of the ECJ has created important uncertainties. Given the centrality of Regulation 1408/71 in the free movement of patients, these decisions have robbed it of much of its certainty. Consequently it seems necessary to undertake a revision of the whole legal framework regulating access to health care across the European Union. Since the issue is now attracting much attention - especially in countries where patients are confronted with waiting lists and other difficulties with access, and key actors are experimenting with new ways of meeting patients expectations, including across borders, some guidance is needed.

In the same way, , the growth of electronic commerce also creates challenges to health policy, as recognised by the Council of Ministers' call for information technology to be implemented in the health sector in ways that promote social inclusion. The EU has taken a number of measures to protect consumers in the information society, both legislative and non-legislative initiatives. Many of these measures indirectly affect certain aspects of health care systems, in so far as they concern data and database protection, security in electronic transfers, distance selling, product liability and quality control. As few were initiated with health care in mind, they may suffer from weaknesses that reduce their effectiveness when applied to health care. Some of the non-legislative initiatives do directly concern the quality and scope of e-health, largely through voluntary or self-regulatory action, and while these initiatives are welcome, their task is compounded by the complexities of ensuring quality on the internet.

The situation with regard to free movement of professionals also creates difficulty. The relevant directives arose at a time whenever a qualification, once awarded, essentially provided a lifetime right to practice. This is increasingly no longer the case and several Member States are instituting mechanisms to restrict registration to those fulfilling certain continuing education requirements. It is far from clear how these are to be treated within the existing legal framework. Furthermore, the principle of mutual recognition, upheld in the Kohll case, effectively precludes the possibility that training programmes in one country may be of a different standard from that in another, despite extensive evidence that this is so.

There is now a jurisdictional gap in the regulation of health professionals in Europe, with enhanced national regulatory structures but an absence of co-ordination at a European level. For many reasons, professional self-regulation prevails in Europe but the bodies involved nationally often have additional functions, which may include education, establishment of professional standards, a trade union function, or others. Unfortunately, in those European bodies that do exist, these roles are often confused.

The pharmaceutical sector creates numerous difficulties as the international dimension is so much greater and the challenge of balancing trade and health policy concerns is especially acute. One example is direct to consumer advertising where there is strong commercial pressure to permit it but sound health policy reasons to reject it. The EU institutions have created a framework in which the supply of medicines to a common or internal market has been harmonised along common lines to the benefit of drug manufacturers (and intermediate suppliers who source their products –parallel imports- from different markets within the EU) even in the face of intellectual

property rights. European law and policy has had much less direct impact on the demand side. Pricing and reimbursement controls as demand side management techniques are only marginally impacted on by EU law - whether primary treaty rules or secondary harmonising legislation. Proxy demand side controls on doctors' prescribing, wholesalers and pharmacists margins are outside the remit of EU pharmaceutical policies. However, e-health and e-commerce could provide many possibilities to break down the traditional single gatekeeper model of access, allowing multiple entry points and the direct distribution of information (of whatever quality) to patients. Whether this will allow the Commission to influence proxy demand and demand more directly remains to be seen.

With regard to medical devices, further adjustments to national regulatory regimes will also be required. For example, although the new Euro-system includes the post-market monitoring protocol many problems remain. While the system may appear stringent, there are still questions about aspects of vigilance and self-regulation. There are also national differences in both reporting and implementation, raising the challenge of how to obtain convergence without compromising the health and safety of patients in countries with stricter provisions, in other words to avoid regulating down to the lowest common denominator, while meeting industrial policy goals. Such national differences will ensure that post-marketing surveillance of medical devices in the EU remains a complicated and difficult process.

Voluntary health insurance is increasingly important in some countries as a means of obtaining access to quality health care within a reasonable time. Here, European policy is dominated by the objective of integrating insurance markets. The existing Community legal framework is based essentially on the logic of free Community-wide competition among insurers whose solvency is supervised and guaranteed by competent authorities in the home Member State, based upon a harmonised set of insurance business conditions and prudential rules. Governments' discretion to materially regulate prices and conditions of insurance products, is seriously reduced as this could impede fair competition among European insurers and could jeopardise the financial health of insurance undertakings. In the field of health care this constrains Member States' options to expand the role of voluntary health insurance while maintaining principles of solidarity. Article 54 of the third non-life insurance directive, introducing the possibility of exemption based on the general good, is unlikely to meet the regulatory needs felt in different Member States.

The application of competition law in the field of health care is also problematic. While many of the transactions within statutory systems may be exempt on social grounds, health authorities must be aware of the possibility of removing this protection through deregulation and privatisation. Health care organisations may be considered as undertakings and this is not affected by issues such as ownership of profit-seeking status. What is important is whether they engage in economic activity.

Moreover, each activity undertaken by an organisation must be judged on its merits; even where most of its activities are deemed to be non-economic, and thus exempt from competition law, it does not follow that everything it does is also exempt.

There are several ways in which activities may qualify as non-economic. They may be sovereign, in other words necessarily performed by the State when exercising official authority. However, the State must show that it is necessary for it to perform this activity, and must exercise caution when delegating its role to other bodies. It may be a social activity, but here it must demonstrate that it involves social protection and is based on the principle of solidarity. It may also be exempt because it involves no identifiable payment or because the activity simply involves the organisation concerned meeting its basic needs to continue to function. However, it is easy to see

how poorly considered health care reforms, especially where they introduce market-mechanisms and decentralisation, might render organisations unexpectedly subject to competition law.

As we have already emphasised, in Europe health care is organised in such a way as to preserve solidarity and promote equitable, effective and efficient treatment. There are many reasons, such as information asymmetry and externalities, why an unrestricted market is unlikely to promote these goals, as is apparent from even a brief examination of the American health care system. In particular, subjecting health care organisations to the full impact of competition law may disrupt the many agreements necessary to provide an equitable distribution of services that is appropriate to population health needs. It risks disadvantaging further the most vulnerable members of society, whose voices are already largely unheard. It is thus apparent that there are many areas in which health policy and the promotion of the single market can either conflict or, more often, create ambiguities.

In the absence of a clear statement of principles on which health care policy in Europe should be based, the ECJ is bound to base its decisions primarily on the imperative to promote the single market. It does recognise the particular circumstances of health care, such as the need not to undermine national systems, but there is a need for much more clearly thought out guidance on what the European Union is seeking to achieve when meeting the health needs of its population within a single market.

Many of these challenges arise from the growing role of the ECJ. Its role is to interpret the application of EU law in specific circumstances but these interpretations then establish precedents that are applied in different circumstances. If member states cannot sway the interpretation of the ECJ, they may still be able to change the European law itself. However, the reality of the joint-decision trap makes it extremely difficult to reverse the ECJ advances based directly on an EC Treaty. Though in theory it should have been easier to change regulations and directives because of the possibilities offered by qualified majority voting, in practice few ECJ interpretations have provoked legislative action to reverse the thrust of the decision.

This is because most ECJ's decisions affect member states differently, so there is no coalition of support to change disputed legislation. The tendency toward juridification may help to weaken the legitimacy of the integration process as a whole. The European Union is already suffering from a form of 'political deficit' to the extent that such actors as the political parties, the trade unions or even the media, whose actions often act as a reference point for national voters, are generally weak at European level.

By camouflaging conflicts of interest and replacing partisan conflicts with supposedly neutral debates on the interpretation of law, it considerably weakens the political process and offers opportunities to opponents of integration to claim that citizen's democracy is replaced by a form of 'judicial democracy'. However, the same process may be seen in a more positive light because litigation at European level can enable European to protect their rights against decisions of national administrations. Nonetheless, ECJ rulings may easily be perceived as intrusions calling in question the choices and traditions of national communities.

The challenge that the EU faces is that its secondary legislation, such as directives and regulations, and the Court's interpretation of them, must be based on what is in the Treaties. However, the social character of European health systems is not embedded in the Treaties.

So what is to be done? This report makes the case for an explicit European health policy, that would bring considerable benefits, setting out an agreed position among Member States on what they are seeking to achieve through their health care systems. There is likely to be sufficient

agreement to reach a common position, at least at the level of principles. Consequently, if the European social model is not to be undermined inadvertently by the inappropriate application of EU law designed to meet needs in other sectors or a piecemeal series of judgements on health care, it will be necessary to agree on a statement of fundamental principles that enshrine the goals of European health systems, that balance the internal market with social goals, and that can be incorporated in a future Treaty.

It must, however, be conceded that difficulties may arise when attempting to develop more detailed policies, given the wide diversity of arrangements in place in Member States to deliver health care. Furthermore, a statement of principles, while constraining unintended and undesirable consequences of the internal market, is insufficient to achieve the benefits that closer European integration offers for health care systems.

A system of open co-ordination, in which there are formally established means to learn from the experience of others while taking account of national circumstances, provides an opportunity to promote best practice, increasing exchange of information on what works and what does not, in what circumstances. In many cases it will be possible to develop shared approaches to common problems but this process respects historical, political and cultural diversity and does not force the process of harmonisation of processes that, while pursuing the same goal, are organised in ways that are incompatible with each other.

An open method of co-ordination will make some of the challenges posed by the internal market for health care systems more explicit. It will also provide a framework within which they can be addressed and appropriate legal responses, including possible Treaty revisions, debated.

These procedures will, however, take time and it is apparent that action is needed now. Consequently, it is of the utmost importance that the EU establish, as soon as possible, a system that can monitor the impact of EU law on health care systems on a continuing basis.