

## CHAPTER 1

# **The Implications of European Law for Health Care**

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In a Europe that is becoming ever more integrated, the place of health care in European law is increasingly unclear. From the earliest days of the European Community, health care has been seen as a national matter. While the structures vary in different countries, the financing and delivery of health care have been organised on a national basis. When health began to be included in European treaties it was clearly stated that, notwithstanding the importance of co-ordinating those aspects that had trans-frontier implications, the way in which health care was organised was a matter for national governments, a position that those governments subsequently have guarded jealously. Thus, the recent European Union Charter of Fundamental Rights established a right to medical care but “under the conditions established by national laws and practices”.

Yet this position was always over-simplistic. Health care involves more than the distribution of funds or the building of hospitals. It involves people, whether as staff or patients, both of whom are increasingly mobile as borders fall within Europe. It involves goods, such as pharmaceuticals and technology, which have always been traded internationally. And it involves the provision of services, the nature of which is continually changing, whether due to technical advances, such as the growth of the Internet, or structural developments, as the border between public and private becomes blurred. Inevitably this creates tensions. How does one balance provisions to ensure international freedom of movement with national systems of regulation, whether of professionals or pharmaceuticals, in ways that take account of local circumstances but are not concealed protectionism? How does one enable those seeking care to take advantage of provision elsewhere while not undermining national solidarity?

The expanding scope of European law in areas that impinge on health care, coupled with a greater awareness by individuals and organisations within the European Union of the rights that this confers on them, has exacerbated the tensions and thrown into relief the challenge of ensuring that progress in developing an internal market enhances rather than undermines consumer safety and social protection. Resolving this challenge has become more important as the social dimension of what was first conceived as primarily an economic union has become more prominent.

European law is thus an increasingly important factor in the development and implementation of national and local health policy. Yet for many it remains shrouded in mystery. This is hardly surprising, as the European legislative process appears remote, with little coverage by either the popular or professional media. But the situation with regard to laws impacting on health care is especially problematic as, typically, consequences arise from policies designed primarily to address problems in other sectors, which then establish general principles whose applicability to health care only becomes apparent once interpreted by rulings of the European Court of Justice (ECJ). As the Court can only rule on the precise situation that has been presented to it, this means that the broader implications for health care are often unclear and highly contentious. Thus, initial rulings applying the Treaty freedoms to health services and products were held by many to be limited solely to health systems such as that of Luxembourg, from which they arose, that functioned on the basis of initial payment by the patient with subsequent reimbursement. It required a later judgement to clarify that health systems in which services were provided directly were also included.

In December 2001, during the Belgian Presidency of the European Union, Mr. Frank Vandenbroucke, the Belgian Minister for Social Affairs and Pensions, convened a conference in Ghent on the implications of European law for the social nature of health care. Two complementary books emerged from this process. This one provides an in-depth analysis of some of the most important issues facing health policy-makers in Europe, in which leading commentators provide their perspectives on the current situation and prospects for the future. Inevitably, while there is a high degree of consensus, there are areas where analysis (or interpretation) of the situation differ, reflecting the complex reality that presently exists. These chapters provide a detailed map of the often-labyrinthine body of European law, from a range of perspectives.

In a sister volume we have attempted to explore what these issues mean for the social nature of health care in Europe<sup>1</sup>. Despite differing in the detail of how they are organised, Europe's health care systems are united by the principle of solidarity. Yet, as the contributors to this book show, there are often tensions between free movement and social solidarity. How can these tensions be resolved? Is the present legal basis of the European Union sufficient to achieve this? We argue that it is not, and elsewhere we argue for the development of an explicit European health policy, based on a revision of the Treaties, and incorporating formal systems for co-ordination so that all can benefit from best practices wherever they arise. For now, however, it is essential that policy-makers be informed of the potential implications of European law for their work. This book seeks to provide this information.

The one health related area where the European Union has a clear competence to act that is enshrined in the treaties is public health. However, that competence is tightly constrained, with scope for action primarily limited to measures involving co-ordination of policies as well as a requirement to ensure that health is taken into account in other European Union policies. Yet, as Hervey notes in Chapter 2, an appearance of weakness in these provisions may lead observers to underestimate their impact. She shows how the European Union has often been able to go beyond what had been thought possible, developing programmes such as Europe against Cancer and Europe against AIDS, and argues that instruments of soft law (non-binding legal instruments) may be more significant forces for integration than might be thought. Thus they may provide a reference point for measures of hard law. They may promote convergence through expression of agreed recommendations, which may in turn prompt voluntary changes that bring national systems in line with an agreed "European norm". They may identify areas of "Community concern", where formal legal competence is lacking, thus paving the way for future developments in Community action, sometimes leading to enactment of binding legal measures. In this process, norms and policies promulgated at the European level interact with national norms and policies, contributing to the emergence of a multi-level European health policy.

Public health is not, however, an issue that has attracted widespread political interest in Member States. Instead, health and social affairs ministries have been more exercised by issues such as movement of patients across borders. In the past few years a series of rulings have challenged the previous consensus that non-urgent treatment abroad

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<sup>1</sup> Mossialos, E. & McKee, M. with Palm, W., Karl, B. and Marhold, F. (2002), *EU Law and the Social Character of Health Care*, P.I.E.-Peter Lang, Brussels.

would, in most circumstances, require prior authorisation by the organisation responsible for paying for it. As Nickless shows in Chapter 3, this is no longer the case. He traces the evolving legal situation concerning free movement of patients, describing in detail successive rulings and showing how they have raised as many questions as they have answered. In reaching its decisions the Court has balanced many, often competing, objectives. These include supporting the right of free movement while protecting the finances and configuration of national health care systems and endorsing a Europe-wide approach while accepting the principle of subsidiarity. A particular challenge is definitional: precisely what are the boundaries of the health care system, as they differ widely between countries in terms of who is covered, for what, and by whom? But an even greater challenge is how to address issues of health care in the context of an internal market. Nickless reminds us why the principles of the market cannot be applied to health care, noting in particular the need for cross-subsidies if those in most need are to receive the care they require, as well as the high level of information asymmetry that exists.

In Chapter 4, Jorens explores this evolving situation further, focusing on the implications for patients seeking treatment abroad. Noting how patients are increasingly able to decide for themselves whether they wish to obtain health care abroad, he examines the extent to which the ECJ has permitted movement without prior authorisation. He notes how, while it was initially thought that this would not apply to hospital care, this is too simplistic an interpretation. Restrictions on the freedom of movement are only allowed if they are indispensable in providing a balanced hospital service accessible to all and must take account of the principle of proportionality, in other words, is the action being considered proportional to what it seeks to achieve? He questions what is considered as a hospital, given the increasing diversity of settings in which often complex care is provided.

While a long waiting list might be a justification for seeking care abroad, again the criterion of proportionality has to be taken into account and it remains unclear what is understood by the phrase “undue delay”, which is incorporated in the relevant regulations.

While Member States are not obliged to reimburse the cost of treatment that is excluded from their national benefit package, a new consideration arising from a recent ruling is that the reimbursement criteria must be based on objective, non-discriminatory criteria. This means that the decisions on what is covered cannot only be judged at a national level, but must instead reflect an international perspective on effective care. Thus, the Court has introduced an international benchmark that is a first step towards a set of European standards, something

that could emerge from the oncoming open process of co-ordination in the field of health care.

In Chapter 5, Hatzopoulos examines the consequences of EU law on state and public procurement for health services. He reminds us how the EU formally has limited competence to regulate health care services. The Treaty provisions provide a very weak legal basis for common action. However, the ECJ has progressively established how the Treaty provisions on the fundamental economic freedoms have a considerable impact on the organisation of health care services within Member States. He shows how the Court, in a series of controversial judgements, has established that health care services do qualify as “services” within the meaning of the Treaty. The Court went out of its way to decide that the free provision of such services, and indeed all the “free movement” provisions, should be assured under any circumstances, even where they are provided as part of, or financed by a social security scheme. The Court, however, acknowledged three series of exceptions to the above general rule. First, activities, which, by their nature and by the way they are set up constitute the core expression of the State’s responsibility towards its citizens, expressed by the degree of solidarity they embody, may escape from the application of the Treaty rules. Second, overriding reasons of general interest, such as the maintenance of the financial balance of a national social security system, may justify restrictions to the Treaty freedoms. Third, restrictions may be permitted on grounds of public health.

The rules on both state aid and public procurement prohibit the discretionary and discriminatory allocation of public moneys to undertakings operating in a market environment, thus creating artificial market conditions. Hence, it is crucial to examine, for each one entity involved in the provision of health care services, whether and under what circumstances it may be viewed as an undertaking, or as an entity managing public moneys (*i.e.* public authority, contracting authority or other entity controlled by the State). In view of the specific nature of health care services and their linkage to the social security systems of Member States, he argues that it is impossible to draw sharp distinctions. Therefore, according to the criteria used by the Court, it would seem that a) treatment providers, b) hospitals and clinics and c) medical associations would, more often than not, qualify as undertakings. In contrast, central health authorities of Member States would qualify as state entities. The position is extremely finely balanced in relation to the activities of health insurance funds, which, depending on the way they are organised and governed and on the way they collect contributions and award benefits, may qualify either as undertakings or as state entities.

Consequently, there is a risk that money transferred within the framework of a social security scheme from one entity to another could be treated as a state aid when one of the entities involved qualifies as an undertaking and the other as a public authority. Thus, the ECJ has ruled that when the body managing social security contributions imposes reduced charges to some categories of undertakings this can constitute state aid, a view shared by the European Free Trade Association (EFTA) Court in a similar situation. By the same logic, the ECJ has ruled that for a social security fund to accept deferred payment of charges due from an undertaking also constitutes a state aid. These cases show the vigilance that the Commission applies to all forms of fund transfers between the entities involved in the provision of health care and emphasises the need for national systems to comply with EC rules.

He then considers rules on public procurement, noting how many of the entities involved in the provision of health care services are “contracting authorities” in relation to the Public Procurement Directives. Thus, the Court has ruled that a sickness fund in Austria remains subject to the rules on public procurement even when it wants to contract for a commercial activity that is offered within a competitive environment such as the reimbursement of the transport of patients.

It is thus apparent that national health systems must comply not only with general Treaty provisions, but also with specific rules such as those on state aid and public procurement. This, in turn, underlines the need for explicit definitions so that national authorities receive clear guidance as to what is permitted and what not under European law. This is unlikely to happen as long as the legal situation is evolving in a piecemeal fashion from a series of Court rulings, each addressing a specific situation but of uncertain generalisability.

In Chapter 6, Karl examines these issues further, with special reference to competition law. In particular she notes that, 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. She notes how health care organisations can be considered as undertakings and that issues such as ownership or profit-seeking status do not affect this. 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 exempt.

She then examines those ways in which activities may qualify as being 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.

One area where the legal situation is especially unclear is voluntary health insurance. Although only a minor component of health care financing in many countries, where it supplements national systems of social insurance, its importance is constantly growing. Policies to contain public health care costs have shifted part of the cost to households and, in some countries, supplementary health insurance is almost indispensable to achieve access to quality health care within reasonable time limits. Consequently, several countries have taken legal steps to ensure full coverage of vulnerable groups. At the same time, employers are taking an increasing interest in provision of collective health insurance benefits to their employees.

Unlike social insurance, voluntary health insurance has long been considered as primarily an economic activity, and so subject to the application of European law on the internal market. In Chapter 7, Palm shows that, although the European Union's regulatory framework, based on the third Non-Life Insurance Directive, recognises the specific nature and social importance of private health insurance that partially or completely substitutes for health cover provided by the social security system, it is unclear how far Member States can determine the method of operation of health insurers operating on their territory.

In the context of the integration of insurance markets, the non-profit mutual health funds, who have traditionally played a crucial role in securing health cover irrespective of financial and health status, face difficulties in preserving the principle of solidarity. Their specific legal status recognises their social mission and their broadly-based role, which includes involvement in activities related to health promotion, social cohesion, solidarity and reducing social inequalities in health, yet these are increasingly challenged as being market distortions and unfair competition. But the competition rules contained in the EC Treaty are intended to further all the Treaty objectives, including the goal of ensuring a high level of social and health protection. The challenge, as Palm notes, is how to achieve this.

Chapters 8 and 9 take us into the arena of trade in goods, specifically pharmaceuticals and medical devices. In Chapter 8, Hancher explores the evolution of the harmonisation of regulatory procedures for medicines for human use, as well as competition and free movement issues. The application of EU law to the pharmaceutical sector and, in particular, the rules on competition and free movement have been the subject of considerable commentary, analysis and controversy in recent years. This reflects the wide range of European legal problems, often raising novel issues, which have involved the pharmaceutical industry. She focuses on the interconnection between regulatory competition and free movement issues, as affected by evolving secondary legislation and Court rulings.

Important matters relating to the development and gradual harmonisation of the Community authorisation procedures, as well as advertising and marketing are now subject to increasingly complex bodies of secondary law. She also looks in some detail at recent case law, with respect to the application of the regulatory framework to generic products and parallel imports – the two main drivers for competition in the pharmaceuticals market.

She then examines further the legal and policy aspects of Community intervention in the controversial issue of industry pricing strategies as well as national regulatory controls with particular reference to the findings of the recent report by expert economists on the competitiveness of the European pharmaceutical industry. The report, entitled “Global Competitiveness in Pharmaceuticals: A European Perspective” commissioned by DG Enterprise, argued that the European industry has declined in competitiveness compared to the USA, albeit that there are large differences and trends across the Member States. It suggested that many national European markets are not sufficiently competitive, and that the nature and intensity of competition in final markets is too weak to nurture efficiency and innovation. Publication of this report, coinciding with the Commission’s review of the current legal procedures for marketing or licensing products on the European market, raises many complex issues. Publication also coincides with important legal challenges to the Commission’s powers to regulate the activities of pharmaceutical firms who seek to impose dual-pricing systems or other methods of sealing off competition from low-priced markets. She concludes that a reorientation in Community policy may well be timely: in the past the Commission has focussed on the supply side of the market, leaving the demand side essentially to the Member States. She proposes that the possibilities offered by information technology could be harnessed to change this approach in the future.

In Chapter 9, Altenstetter examines the regulation of medical devices in Europe, emphasising the similarities and differences of medical devices and prescription drugs; the timing of European Union medical device regulation; the nature of medical devices and drugs; and the distinct pathways to market authorisation as well as the boundary issues between the two sectors. She discusses the erosion of the boundaries between exclusive and shared responsibilities of the EU and Member States and argues that national medical device vigilance reporting systems and post-marketing surveillance are the weakest link in the European Union process. She asks whether the claim that patient safety is as important in the European regulatory regime as is free movement and competitiveness is really credible? If so, she argues, it will be necessary to make available additional resources. If patient access to effective, safe and high-quality medical devices is to be achieved then a series of other measures must be considered: how to achieve more coherence in the choice of European Union and domestic policy tools; how to produce information on compliance with European Union policy on vigilance and adverse incident reporting that is accurate, timely, reliable as well as comparable and available to the public; and how to make European Union decision-making in more committees more transparent and accountable?

Taken together, the contributors to this book demonstrate the complexity of European law as it relates to health policy, identifying many areas of ambiguity and contention. This situation is clearly far from satisfactory. But what is to be done?

One way forward is to take advantage of a new approach adopted at the Lisbon Council to address areas where there is considerable national diversity, but common goals. This is the “open method of co-ordination”, a way of exchanging information on best practice and achieving greater convergence. It involves setting guidelines, combined with specific timetables for achieving the goals; establishing indicators of best practice; translating European guidelines into national and regional policies by setting specific targets and adopting measures that take account of national and regional differences; and periodic monitoring, evaluation and peer review organised as mutual learning processes. Thus, even without a legal basis to act in the area of health care, the open method of co-ordination can be seen as a compromise between integration and simple co-operation.

Ultimately, however, we believe that there is a strong argument for ensuring that health policy is considered explicitly during the next revision of the Treaty. There are too many areas in which internal market and social goals come into conflict. Including a clear statement concerning the social goals of health care in the Treaty, to which all

Member States should be able to agree given the coherence of their existing domestic policies, would enable the Court to draw on a counterbalance to existing provisions on the internal market.

Until then, however, we hope that the material in this book will contribute to a better understanding of this complex area, so helping to ensure that European law acts as a help rather than a hindrance to those trying to improve the quality and accessibility of health care for which they are responsible.