# Part I

# Introduction

# The European Union and health services – the context

Matthias WISMAR, Reinhard BUSSE and Philip BERMAN

**Abstract.** With some exceptions, health policy has always played a minor role in European integration. A formal policy mandate in the area of public health was introduced with the Maastricht Treaty, which came into force in 1993. As health services were explicitly excluded from this mandate, there appears to be a contradiction to the Single European Market. Not surprisingly, research has therefore investigated various aspects of European integration in regard to its impact on health services since the early 1990s. While this research has contributed towards the understanding of the relation between the European Union and health services, an overall assessment of the impact of European Integration on health services of Member States is still missing.

## 1. The European Union and health policy

Health policy has always played a subordinate role in the course of European integration. Nevertheless, in some specific cases, health issues have been addressed. Elements of a policy for the protection of workers' health and safety were already introduced at the beginning of the fifties within the framework of the European Coal and Steel Community (ECSC). Health protection was also given early consideration in the European Atomic Energy Community (EURATOM), particularly in regard to the protection against ionising radiation. Aspects concerning health policy can also be found in the policies of the European Community (EC), but their significance tended to be of minor importance and focused on public health excluding health services regulation, financing or delivery.

The current structure of the European Union (EU), as depicted in Figure 1, comprises the three Communities pillars, namely the ECSC, EURATOM and the EC; Common Foreign and Security Policy; and Co-operation in the fields of Justice and Home Affairs. The three Communities have common institutions: the European Parliament, the Council, the Commission, the European Court of Justice and the Court of Auditors. Common Foreign and Security Policy and Co-operation in the fields of Justice and Home Affairs are not governed by the common institutions, but are developed directly by the Member States. The EU is to be understood as encompassing all these areas, the Communities and the latter two fields of policy. The research findings gathered in the chapters of this book exclusively focus on the European Community and its predecessor, the European Economic Community.

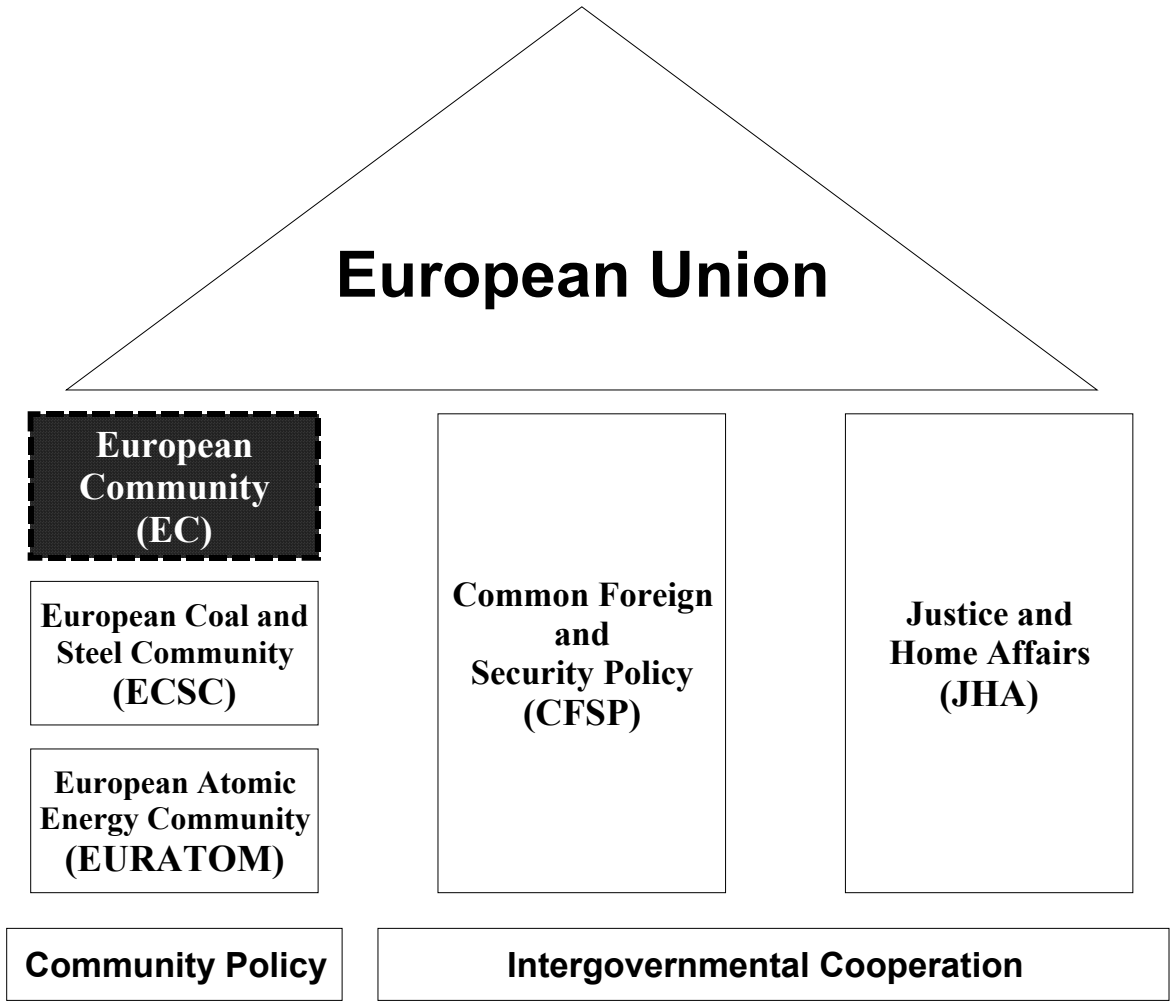


Fig. 1: The European "temple"

This institutional setting was established by the Treaty on the European Union (the Maastricht Treaty) which came into force in 1993. The objective of this Treaty was the fundamental reform of the existing Treaties and particularly the Treaty Establishing the European Community (TEC), which represents the core document of the European Community and contains the major legal provisions establishing the Single European Market (SEM). The SEM was established in its current form through the Single European Act in 1986, which aimed at the completion of the SEM by the end of 1992. The development of the various Treaties and elements of the European integration are represented in Figure 2.

In regard to health and health services, the Maastricht Treaty is of particular importance as it gave the Community concrete legal competencies related to health through two new provisions. First, Article 3(o) empowered the Community to "contribute to the attainment of a high level of health protection" for its citizens. Second, Article 129 repeated this objective ("Health protection requirements shall form a constituent part of the Community's other policies.") and outlined specific areas of competence to achieve such an objective, namely "the prevention of diseases, in particular the major health sources, including drug dependence" through promoting "research into their causes and their transmission, as well as health information and education" and "encouraging cooperation between the Member States and, if necessary, lending support to their action".

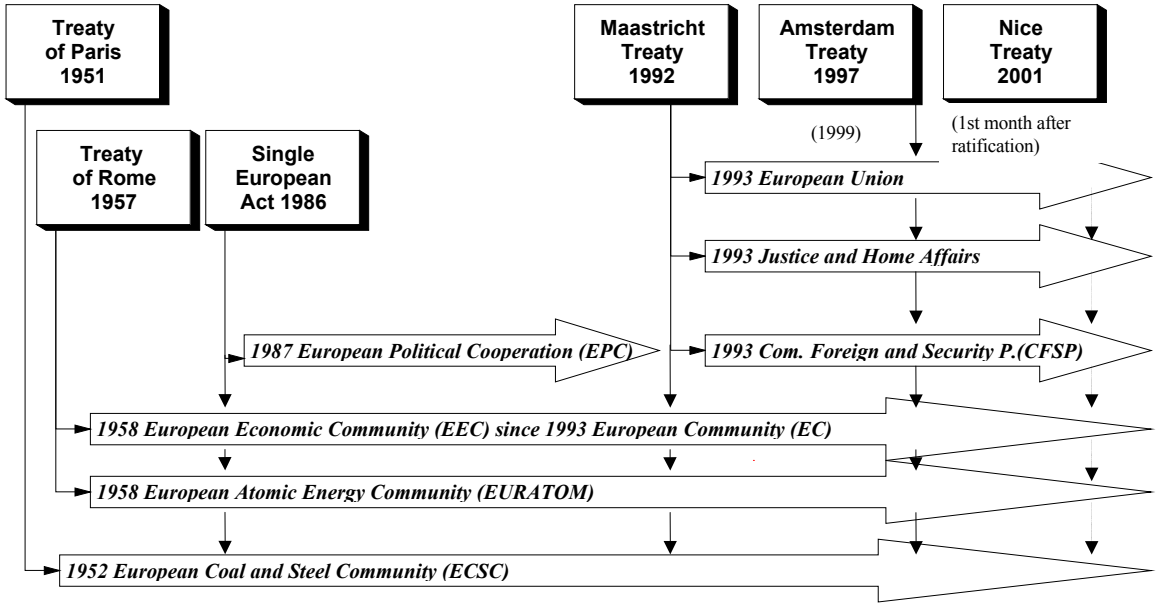


Fig. 2: Development of the treaties

This mandate on (public) health was renewed and slighly revised (mainly in response to the BSE crisis) in the renumbered Article 152 at the summit of Amsterdam in 1997. The "Amsterdam Treaty" was signed on 2 October 1997 and has been in force since 1 May 1999. Currently, the Treaty of Nice which will amend the Treaty on European Union and the Treaties Establishing the European Communities and certain related acts is in the process of ratification[1] and will come into force one month after this process has been finalised.[2]

Table 1 presents an overview on all articles in the Treaty in its Amsterdam and Maastricht versions which are directly related to health. With the exception of Article 137, none of the health related articles in the TEC will be changed by the Treaty of Nice. And, while Article 137 is both broadened and specified, the health aspect remains unchanged.

It should be noted, that the health related articles in the Treaty have differing characteristics. While Article 3, paragraph 1 (p) in particular, and to a certain extent Article 95, paragraphs 3, 6 and 8 as well as Article 186 formulate a general health related mandate, Articles 137, 140, 152, 153 and 174, paragraph 1 provide legal provisions for specific actions only. Other articles, however, refer to health as a reason to restrict other legal provisions in the Treaty.

What is basically a broad mandate on health policy, though, comes up against clear limits in the prevailing interpretation of the legal framework. The subsidiarity principle set out in Article 5 is invoked as a basic principle. In the areas which do not fall within its exclusive sphere of competence, the Community only becomes active if and when it is clear that their objectives cannot be realised by the Member States and can only be achieved effectively at a Community level.

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[1] At the time of writing, the Treaty of Nice has not yet been ratified by Belgium, Greece, The Netherlands and Sweden. In a referendum on the Treaty, Ireland voted against ratification.

[2] Since the amended TEC is not yet in force, the general rule is that articles in the TEC will be quoted by the version of the Treaty of Amsterdam. Reference to other versions of the Treaty will be made when appropriate and indicated in the text.

Table 1: Anchoring the EU's mandate on health policy in the EC Treaty

| Article, new version (Amsterdam Treaty) | Article, old version (Maastricht Treaty) | Contents/ significance for public health |
|---|---|---|
| 3 par. 1 (p) | 3 (o) | a contribution to the attainment of a high level of health protection |
| 30 | 36 | restriction of free movement of goods on the grounds of health |
| 39 par. 3 | 48 | restriction of free movement of workers on the grounds of public health |
| 46 par. 1 | 56 | restriction of the right of establishment on the grounds of public health |
| 95 par. 3 | 100 (a) | attainment of a high level of health protection in the approximation of laws |
| 95 par. 6 | 100 (a) | extension of the approximation period in the absence of danger for human health |
| 95 par. 8 | 100 (a) | Member States obligation to notify specific public health problems in a field which has been the subject of prior harmonisation matters |
| 137 | 118 | improvement in particular of the working environment to protect workers' health and safety |
| 140 | 118c | prevention of occupational accidents and diseases |
| **152** | **129** | **public health competencies** |
| 153 | 129a | health protection as part of consumer protection |
| 174 par. 1 | 130 (r) | protecting human health as part of environmental policies |
| 186 | 135 | including public health provisions to the provisions on the association of the overseas countries and territories |

This general subsidiarity principle is specifically reflected twice in Article 152 of the TEC, namely in paragraph 4(c) ("… excluding any harmonisation of the laws and regulations of the Member States.") as well as in paragraph 5 ("Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care."). This is often interpreted as a clear indication that healthcare is not the subject of Community policy and that any kind of intervention or harmonisation of the structures for regulating, financing and delivering medical care on the part of the Community institutions is to be categorically excluded.

In political terms, there appears, therefore, to be a contradiction between the purpose of the Single European Market (SEM) and the manner in which the statements in Article 152 are widely interpreted. However, the inherent dualism in the TEC between an integrated SEM on the one hand, and health services with their national borders on the other has to be called into question on theoretical grounds. After all, the free movement of persons, goods, services and capital, as established in the TEC, also involves the principle of unrestricted mobility of doctors, other healthcare professionals, patients, medicines, technical equipment, and direct investments into healthcare facilities in the EU. The allocation of health services to an area which remains impervious to EC legislation and judicial decisions concerning the SEM is therefore implausible.[3]

[3] It was only recently that the German Advisory Council for the Concerted Action in Health Care emphatically referred to the dual function of the health system as a welfare-state sector consuming the wealth of the nation services and, at the same time, a productive branch of industry. Thus the special reports for 1996 and 1997 (Sachverständigenrat für die Konzertierte Aktion im Gesundheitswesen 1996, 1998) bear the title "Gesundheitswesen in Deutschland: Kostenfaktor und Zukunftsbranche" (The Health Care System

## 2. Research on European integration, health and health services

Academic research has only recently begun to turn its attention to the relatively new filed of EU health policy. The purpose of this section is to map European integration and health services as a field of research. The intention is to provide an overview of the research questions and issues in order to set the background for this study and to locate it in its academic context. It is not the intention, therefore, to provide a comprehensive review on the literature.

### *2.1 The completion of the SEM and health services*

With the ratification of the Single European Act, the question of the impact of European integration on health services gained relevance on the scientific agenda. Various topics were highlighted, for example the harmonisation of taxes, in particular VAT, in terms of their impact on financing health services. Other studies focused on the free movement of physicians and nurses, the pharmaceutical sector, medical devices, the export of social benefits, health protection at the working place, and the possibility of cross-border hospital care at border regions. This early discussion of the impact of European integration on health services of Member States also raised concerns – depending on the country perspective – about the likelihood that integration might put pressure on social standards that had been achieved, leading to a reduction in healthcare benefits and health protection or, alternatively, that the integration would exert a nationally undesired upward pressure of social standards (Deppe 1990; Deppe & Lehnhard 1990; Lehnhard 1990; Deppe 1991; Ham 1991; Altenstetter 1992; Sachverständigenrat für die Konzertierte Aktion im Gesundheits-wesen 1992). Like an "overture", this research has introduced important themes which are still relevant for research on European integration and healthcare. Yet, while this research was being carried out, the SEM was not yet completed and important areas, such as data protection or medical devices, were at this time only partially regulated by European law, i.e. the research was necessarily theoretical rather than empirical.

### *2.2 Tracing the legal development Europe's role in health*

Another body of literature attempts to analyse the political mandate on health issues introduced by the Maastricht Treaty in order to arrive at new political strategies for action (Mäder 1995). There are, in addition, studies which consider the mandate particularly from the perspective of administrative law, but also from a historical perspective (Schwanenflügel 1996; Berg 1997). These studies are of great value in providing, for the first time, an overview on health activities of the Community institutions in the field of health policy. However, since these studies approach the subject primarily from a juridical point of view, they are less sensitive towards the outcomes and effects of European legislation on Member States. The analysis of a "hidden agenda" or the emergence of a policy in regard to healthcare is outside the focus of these studies.

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in Germany: Cost Factor and Branch of the Future). Admittedly, the special reports do not consider this dual function and its inherent tension in relation to European integration.

*2.3 Health as an horizontal issue in European integration*

Shortly after the inclusion of the health mandate in the TEC, academic debate started (Ham & Berman 1992). Two strands can be distinguished, the first focussing on the areas and determinants of health (and possibly health services) that the EU should address, and the second looking in the other direction – on the impact of EU health policy on the Member States. A prominent example of the former is the book "Choices in Health Policy – An Agenda for the European Union" (Abel-Smith et al. 1995) which is based on a report for Health Ministers. Following that, systematic attempts by the Commission were made to integrate health requirements into all policies of the EC (Hunter & Hübel 1996). While these attempts were warmly welcomed, there has been criticism that these reports fall short in terms of rigour, because they had – unsuccessfully – to rely on the willingness of all parts of the Commission to provide the necessary information (Coghlan 1996). At the same time, the first publications focusing in the other direction began to appear (e.g. McKee et al. 1996).

Today, many conferences and publications by Member States and various organisations are trying combine the two perspectives. Examples include the conference proceedings of a large conference held in Germany when it held the presidency in the EU (Bellach & Stein 1999) or the annual conferences organised by the European Health Forum Gastein (e.g. Leiner & Schuppe 2001). This broader perspective has also been pursued in academic work (Theofilatou 2000).

*2.4 The "completed" SEM and its impact on health policy*

After "Maastricht", analysis also focused on specific elements of the SEM in regard to health and health services, especially in the areas of medical devices (Altenstetter 1996; Heppell 1996; Altenstetter 1998) and pharmaceuticals (Mossialos 1998; Keck 1999) but also on private health insurance (Bastiani 1995), health protection at the working place (Gerlinger 2000) and the labour market for health professionals (Jinks et al. 2000). One of the reasons that these research projects were undertaken was that new legislation was being introduced to harmonise various aspects of these sectors across the Member States of the EU. In some cases even new institutions, for example the European Agency for the Evaluation of Medicinal Products (EMEA), were being established.

*2.5 Empirical studies on patient mobility*

Prior to the ruling of the ECJ in the cases Kohll and Decker, the subject of cross-border patient mobility was addressed in terms of an assessment of the existing instruments which regulate and facilitate cross-border care within the EU. Empirical studies have focused on the "E 111" procedure which applies to emergency care during short stay abroad (Hermans & Berman 1996; Hermans & Berman 1998), on patient mobility (Hermesse et al. 1997) including case studies, for example on Italy (France 1997) and Greece (Kyriopoulos & Gitona 1998), and on patients' rights to cross-border care (Hermans 1997; Verschueren 1999).

Cross-border healthcare schemes which were set up in the "EUREGIOs" attracted especial interest. There are a number of useful published studies on these EUREGIO: Meuse-Rhine (Starmans et al. 1997; Hofmann & Kochs 1998; Grünwald & Smit 1999); Rhine-Waal (Lottman & Wilt 1999), and overviews on the various schemes (Ministry for Women Youth Family and Health of the State of North Rhine-Westphalia 2000; Mountford 2000; Palm et al. 2000).

Research has not only focused on the actual cross-border flows but also on the administrative mechanisms that facilitate this cross-border flow. Some studies have sought to analyse citizens' and patients' knowledge, attitudes and experience of cross-border care within the EU (Calnan et al. 1997; Calnan et al. 1998; Gesellschaft für Versicherungswissenschaft und -gestaltung 2001).

*2.6 Analysis of ECJ cases on cross-border care*

In April 1998, two preliminary rulings of the European Court of Justice (ECJ) caused a stir among Member States. The two Luxembourg citizens, Kohll and Decker, had obtained goods and services in the field of medical care while abroad. Decker obtained a pair of spectacles in Belgium on presentation of a Luxembourg prescription, while Kohll took his under-age daughter across the border to Germany for orthodontic treatment. When they returned to Luxembourg, both citizens demanded reimbursement from their health insurance funds. This was refused on the grounds that no preliminary approval had been granted (i.e. the E112 form). The argument was that the European directives provided for reimbursement of costs through the competent institution only in cases of medical emergency while on business trips or on holiday, unless preliminary approval had been obtained. A journey with the explicit purpose of obtaining benefits abroad, it was argued, did not fall within the scope of the European directives. The Luxembourg health insurance funds did not therefore see themselves under any obligation to reimburse the expenses. The cases were brought before a Luxembourg court. As the plaintiffs invoked the free movement of goods and services in the EC, the Luxembourg court sought clarification from the ECJ on the interpretation of the Treaty. The outcome is well known. In its decisions of April 28th 1998, the ECJ largely upheld the view of the two citizens from Luxembourg. Since then, a steady stream of cases on cross-border healthcare have been brought before the ECJ. These cases and the rulings of the ECJ have attracted considerable attention and have made clear the impact that the SEM has on health services of Member States.

Clearly, with Decker and Kohll, the volume of literature on the subject has increased with remarkable speed and has now reached almost impenetrable proportions. And the end of this growth is not in sight, since a number of new cases are pending with the ECJ (Wismar & Busse 1998; Mountford 2000; Palm et al. 2000; Wismar & Busse 2001; Wismar 2001).

The ECJ cases have put a number of fundamental issues on the agenda. Some authors have analysed the types of social benefits are in principle subject to European legislation (Füßer 1997). Another issue of real relevance is the future of the benefit-in-kind principle. The argument was put forward that the Kohll and Decker rulings may imply that the option for cost-reimbursement has to be provided at least as an alternative to the benefit-in-kind principle by the competent institution. This would entail a different patient-provider relation (Wille 1999). The ECJ rulings also raised questions concerning the elective in-patient sector, especially since free cross-border mobility of elective patients might result in high expenditure, with the consequent impact on existing budgets and the potential to undermine public capacity planning (Burger 2001). Clearly, this body of literature is not only concerned with the extend to what the free movement of people and services has to be applied to healthcare institutions but also to the repercussions on institutional settings, delivery, management and governance of health services (van der Mei 1998; van der Mei 1999). Related to the court cases there are accounts on the political perception of Kohll and Decker throughout the Member States (Gobrecht 1999).

*2.7 Competition law and self-governing bodies*

Another strand in the scientific and political debate on European integration and health services refers to competition law in the TEC. According to Article 81, all agreements between "undertakings" or their associations which may prevent, restrict or distort competition within the SEM are incompatible with European law. This article refers in particular to direct or indirect price fixing or any other trading conditions. Competition law applies to all undertakings no matter whether they are private or public (Eichenhofer 2001). And indeed, undertakings are not assessed by their formal or legal status but by the function they fulfil.

National health services are less affected by competition law since European competition law does not apply to state activities. But, in Social Health Insurance countries, many tasks are delegated from the Ministry or state institutions either to the self-governing bodies of physicians or to sickness funds. Their status as institutions under public law with a set of explicitly delegated powers does not, in principle, prevent them from becoming subject to European competition law. Not surprisingly, research – mainly by lawyers – is based in countries such as Belgium (e.g. Pieters & van den Bogaert 1997), Germany or the Netherlands.

There are various areas which are currently under debate. For example in Germany the reference price system in the pharmaceutical sector is being questioned. According to § 35 Social Code Book V, the federal associations of the sickness funds have the responsibility to set the prices of the reference price list. A pharmaceutical which exceeds this price ceiling is still available an may be prescribed, but any amount of money above this ceiling has to be paid out of pocket by the patient. It is up to the physician and the patient to make the decision whether a pharmaceutical which is below the price ceiling shall be prescribed. The current discussion focuses on the question as to whether price setting by the federal associations of the sickness funds is incompatible with European competition law since it is suggested that they fix prices and a form of cartel which is incompatible with Article 81 of the TEC (Giesen 2001). To be on the safe side, the regulations regarding the setting of reference prices were recently suspended for 2002 and 2003 in favour of governmental price-setting by ordinance. But the debate on the applicability of European competition law goes far beyond single mechanisms such as the pharmaceutical price regulation scheme. In Germany, it reaches the Federal Committee of Statutory Health Insurance Physicians and Sickness Funds which is performing a variety of highly relevant functions essential to the whole system architecture (Busse 2000). Even the collective contracts between sickness funds and physicians may come under the suspect of cartel building (Eichenhofer 2001). The situation is new insofar as the application of social legislation in the area of social security in Germany had priority over German competition law. But this is not the case for European law which is considered to have priority over domestic law and is instantly applicable (Knispel 2001).

*2.8 Comparing prices, benefits and quality*

It has been argued that with the introduction of the Euro in most Member States, cross-border price comparisons will be made by patients, purchasers and politicians. This might result in an intensified "shopping around" across Europe for best value healthcare (Kücking 1998). Yet, our knowledge on prices and contents of benefit packages in Member States is very limited. Nevertheless initial attempts to compare certain parts of benefit packages have been made (Kupsch et al. 2000). Other studies have focused on specific benefits and price comparisons (Kaufhold & Schneider 2000). Pharmaceutical pricing policies are another

relevant issue in this debate (Mossialos 1998). Cross-border care also raises the question of quality. The ECJ has argued, in regard to Kohll and Decker, that cross-border care does not pose a threat to human health, since a similar standard of healthcare can be expected in all Member States. This opinion was based on the assumption that mutual recognition of diplomas and established minimum training requirements for health professions will guarantee this standard. But not all health professions are regulated by these directives, and it remains questionable if the assumption is valid (Nickless 2001). Undoubtedly, this strand of research has gained new relevance in the light of the ECJ court cases.

*2.9 European integration, healthcare and policy development*

The completion of the SEM, the Interreg programmes and the Maastricht Treaty have all raised awareness and interest in the political arena about the relationship between European integration and health and healthcare. This interest has certainly intensified with the Kohll/Decker rulings and more recently with the Peerbooms case. Border regions in particular attempted to respond proactively to the new developments by supporting cross-border health planning and delivery, for example in the German "Land" of North Rhine-Westphalia and its neighbouring regions in the EU (Sendler 1996; Ministry for Women Youth Family and Health of the State of North Rhine-Westphalia 2000). During the last German presidency of the EU the Minister of Health acknowledged the impact of European integration (Fischer 1999).

In the Social Health Insurance countries – Austria, Belgium, France, Germany, Luxembourg and the Netherlands – the self-governing bodies and their associations investigated this matter. There is, for example, a study on the Austrian social security system's compatibility with European economic regulations (Schulz-Weidner & Felix 1997). In the Netherlands, at the request of the Council of Health and Social Services, a report was commissioned to assess the scope, risk and chances of the SEM in healthcare (Belcher 1999). The resulting main report by the Council came to the conclusion that the Dutch health system is facing major challenges (RVZ 1999). In order to reach political conclusions, the SEM in healthcare for purchasers, providers and patients has also been analysed in Germany (Gesellschaft für Versicherungswissenschaft und -gestaltung 1996). The working committee of the federal associations of sickness fund in Germany has agreed on a common position in regard to the ECJ rulings (Arbeitsgemeinschaft der Spitzen-verbände der gesetzlichen Krankenkassen 2000). Various sickness funds in Germany have made attempts to develop positions (Klusen 2000; Lorff & Maier-Rigaud 2000).

Clearly, the impact of the SEM, European competition law and the EU health mandate on health services in the Member States is not only an academic affair, it is of relevance for the various actors in the domestic health policy arenas.

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# The Single European Market and health services - the research design

Philip BERMAN, Reinhard BUSSE, Matthias WISMAR, Bie Nio ONG and Calum PATON

**Abstract.** This chapter describes first the three phases of the project and their objectives. It then explains how the four freedoms of persons, goods, services and capital were broken down into 14 analytical categories (e.g. labour market for doctors and dentists, pharmaceutical market, consumer choice services). Furthermore, definitions on terms are given, e.g. that *impact* refers to the effect of SEM interventions upon domestic legislation and the administrative rules of national or regional institutions while *outcomes* are defined in terms of effects on health services or healthcare. The final sections give details about the methods and research strategies used in the three phases; particular emphasis is given to the scenarios developed in phase 3.

## 1. Purpose and structure of the project

The purpose of the project was to analyse the impact of the EU Internal Market – or Single European Market (SEM) – on the regulating, financing and delivery of health services in the Member States. While the Treaty Establishing the European Community (TEC) defines several areas of competence for the European Union with potential impact on healthcare and health services, this project is concerned only with the SEM, with its four freedoms i.e. the free movement of persons/ individuals; the free movement of goods; the free movement of services; and the free movement of capital. The project did not therefore deal with other areas such as competition law, agriculture, social protection, environmental policy etc. Neither did it deal with public health measures, research on health, or health policy under EU programmes (Figure 1).

The study was an international research project conducted in three phases, each aiming at achieving two main objectives:

*Phase 1*

- To identify SEM regulations and directives as well as respective European Court of Justice (ECJ) decisions which explicitly refer to health services and which therefore are classified as having a potential impact on the purchasing, supply and delivery of health services.
- To identify both the methods used as well as the actual extent to which these EU directives have been transposed into the laws and rules of the Member States, whether at national or regional level.

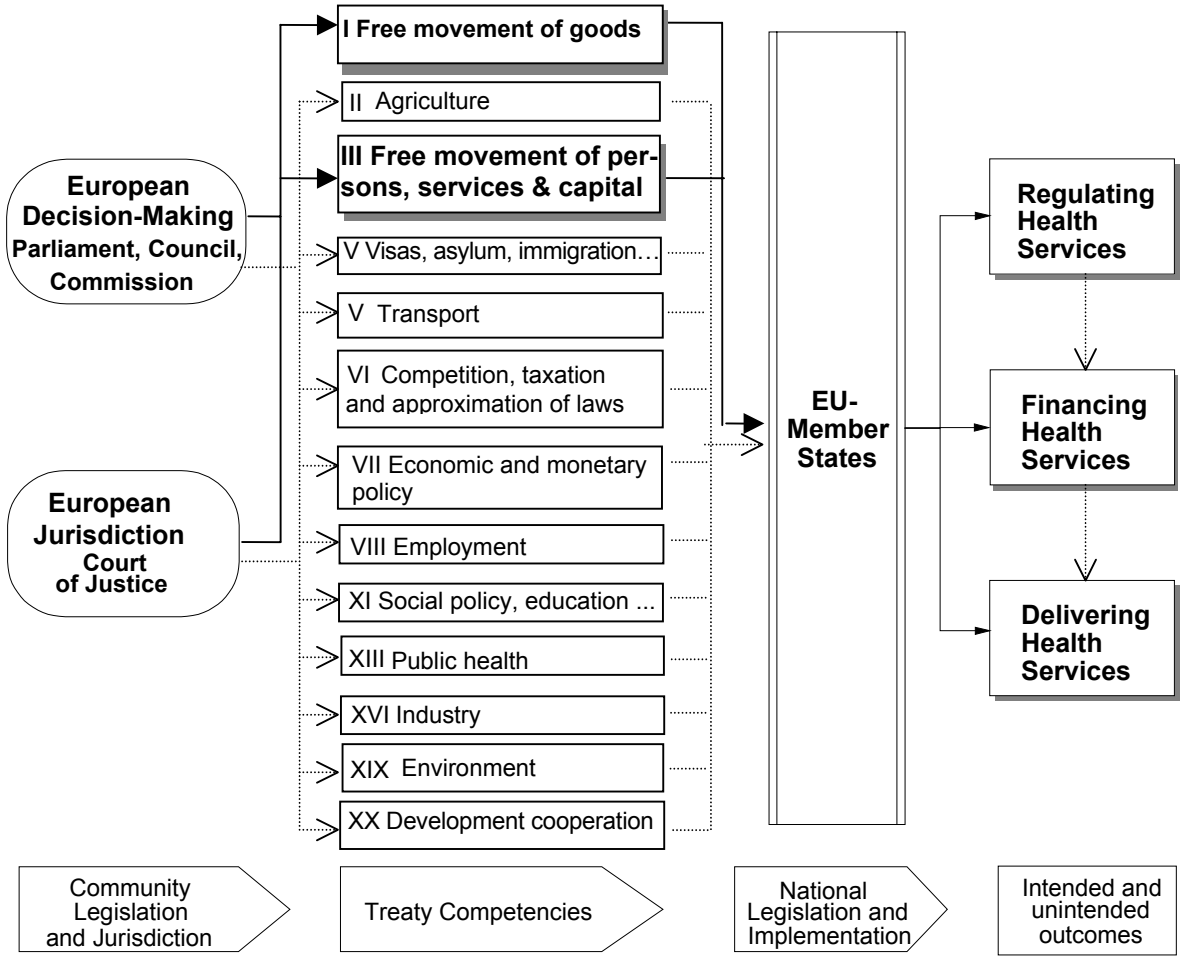


Fig. 1: Design of the study to estimate the effects of the Single European Market on the health services of the Member States

*Phase 2*

- To analyse the factors involved in the extent to which EU regulations have been adopted.
- To evaluate the impact of these national or regional laws and rules on the purchasing, supply and delivery of health services (i.e. to what extent has policy in Member States been changed?).

*Phase 3*

- To identify outcomes, including both intended and unintended effects, of the SEM on Member States' health services and to develop futures scenarios exploring key issues identified in the earlier analysis and evaluation; and
- To produce an overall report highlighting and analysing the key issues.
- To explore whether duration of EU membership also has an influence on the impact of SEM interventions, four countries were selected for the project to represent the "four waves" of membership of the European Union. Germany represents the original membership group from 1952/58; the UK the first accession group of 1973; Spain the southern expansion in the 1980s; and Sweden the accession countries of 1995.

The design of the study (Figure 1) is intended to cast light on the individual research stages and to illustrate the ways in which they are inter-related. The investigation firstly focused

on all legislative acts and court rulings issued by Community institutions ("European interventions"), in particular the elements of SEM legislation and court rulings which explicitly affect aspects of regulating, financing or delivering health services of the Member States. To explore the effects of the four freedoms on health services, relevant categories were defined for each of the four freedoms.

In Phase 1, the relevant European interventions – i.e. those referring both to health services and the SEM – were identified and categorised. In addition, the measures for their implementation and transposition in the Member States were identified and analysed.

In Phase 2, the outcomes of European interventions and their national transposition were considered to be of particular importance – such as mobility of medical manpower and the free movement of goods and services (or consumers of healthcare moving across national boundaries as part of consumer choice of goods and services). Each case study focuses on the issues that are of particular relevance to one country. For example, consumer choice has been based in Germany; medical manpower has been pursued primarily in the UK; public procurement in Spain; and pharmaceuticals in Sweden. Where appropriate, the case studies have incorporated brief information from the other three countries to provide a broader picture of the impact of EU regulations and policy.

In Phase 3, some of the topics were developed into *scenarios*. The scenarios seek to depict – at a very broad and general level – "alternative futures", based upon different assumptions about the behaviour of key actors and events. The scenarios are not full-blown, data-based scenarios but attempts to provide a basis for future policy by EU and Member State policymakers – by drawing attention to the possible consequences of different courses of action or inaction.

The chapters in this book present a selection of these case studies and scenarios.

## 2. Definitions

The term *intervention* includes both policy instruments (directives, regulations etc.) and the juridical instruments by the European Court of Justice.

In assessing the relevance of a single piece of legislation or jurisdiction, the terms *penetration power*, *outcomes* and *impact* are used. *Penetration power* refers to the degree a given intervention is binding on the national and regional level of Member States. For example the penetration power of a regulation is higher than that of a recommendation since the first is a binding legal instrument which the latter is not. Nevertheless, the *outcomes* of the same regulation could be smaller, if it aims at a very limited and detailed issue, while the recommendation may have a more relevant outcome, since the issues it refers to are of great importance to the health services of Member States.

A further distinction is made between the *impact* of SEM interventions and *outcomes* in terms of effects on health services or healthcare (Figure 2). *Impact* refers to the effect of SEM interventions upon domestic legislation and the administrative rules of national or regional institutions. Impact on Member States depends on a number of factors, including the extent to which directives are transposed, and the extent to which health system rules of Member States are changed. The same EU intervention may have different impact in different countries. For example, one country may already have all the data protection legislation required, while another country may have to introduce a considerable body of legislation.

Equally, countries may transpose legislation more or less effectively (or, in extreme cases, not at all). Full transposition can be explained in a number of ways: a political culture

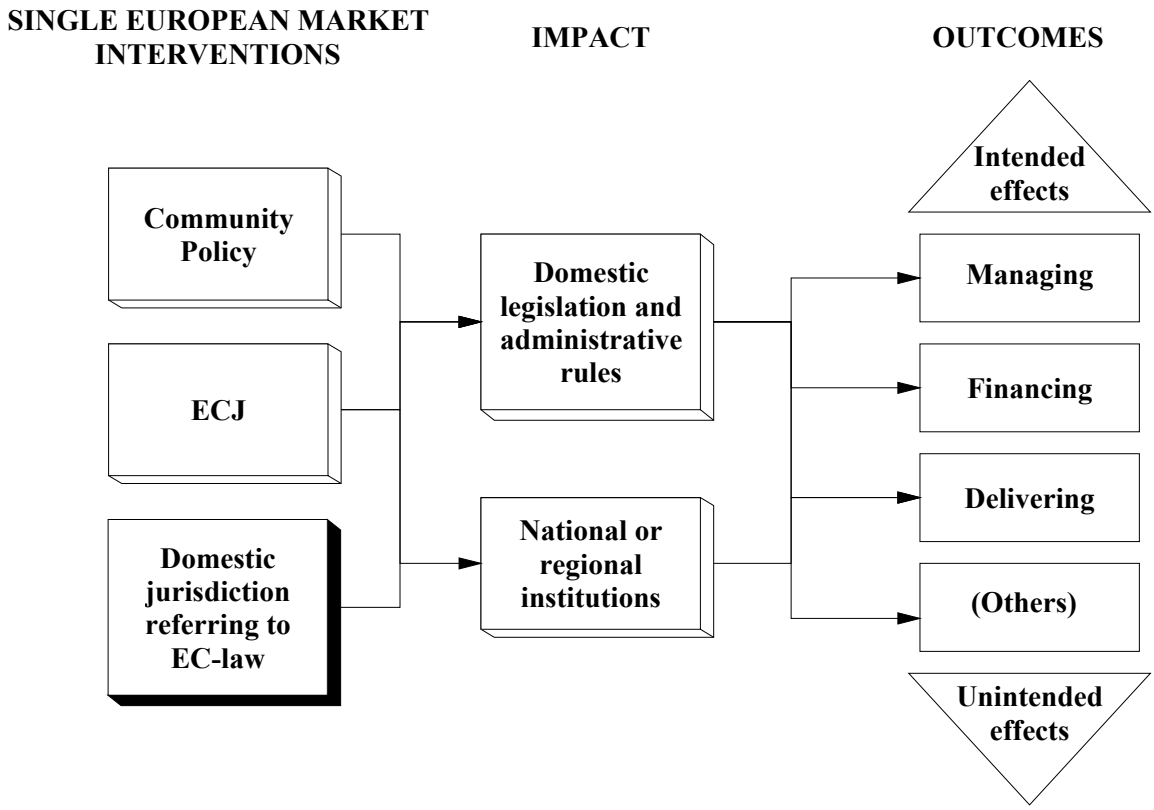


Fig. 2: Relation between interventions, impact and outcomes

of enthusiasm for Europe ("being a good European"); an "automatic" process of transposition of regulations; or the perception that regulations offer national advantage.

The process of transposition differs from country to country – not least reflecting differences between unitary states (such as England); federal states such as Germany; and states such as Spain with varying regional autonomy. One must equally distinguish between formal transposition and implementation within the health sector. Equally one must distinguish between transposition and impact: it is possible to have full transposition but little impact and only partial transposition yet significant impact. Differences may be explained, for example, by the fact that the requirements of the European intervention a) were already covered by national or regional law, b) caused a modification of existing law, c) introduced a completely new set of national or regional law, d) were an opportunity to introduce national and regional law which goes beyond the requirements of the European intervention or e) were of considerable relevance for a national health service but not for a social health insurance system.

*Outcomes* refer to the effects of SEM interventions on health services and healthcare – in terms of management, finance, supply and delivery, i.e. they address the overall question what difference European integration makes for health services. Effects may be intended or unintended. The principal intended effect of each intervention, according to the selection criteria mentioned above, is to establish a SEM. Clearly, some of the interventions have more specific objectives but they will be described and analysed when appropriate. Unintended effects are those which do not comply with the SEM, which are indifferent towards it, or which have negative consequences for health services. The study paid particular attention to these effects and to the different perspectives of the EU and the Member States.

## 3. Formation of categories

To explore the effects of the four freedoms on health services, relevant categories were defined, taking both "supply" and "demand" factors into account (Figure 2). These needed to be sufficiently abstract to represent different health systems and sufficiently specific to enable the formation of meaningful categories.

For example, the free movement of individuals comprises both the free movement of doctors, nurses and other healthcare professionals as "suppliers" of health services as well as of persons undergoing short-term stays (business trips, tourism) or long-term stays in other countries who may "demand" health services during those stays.

In contrast, movement of consumers with the explicit intention to receive healthcare goods or services is classified under free movement of goods and services, respectively, to reflect the intentions of the respective SEM interventions. The other important demand-side categories regarding these two freedoms relate to public procurement, while regulations regarding the pharmaceuticals, medical products and health insurance market constitute the supply-side. As regards the free movement of capital, only one category, namely investments in hospitals, was addressed as a potentially relevant topic for health services.

The definitions of the categories were initially developed in an abstract form and agreed upon in a triangulation process among the participants of the project in order to obtain a consistent interpretation. They were refined in the light of the data that had been gathered.

In summary, Figure 3 presents a typology devised to explore relevant legislation and issues. This typology is not the only possible way to organise the study, but is a robust means of reflecting on the impact of the SEM on health services.

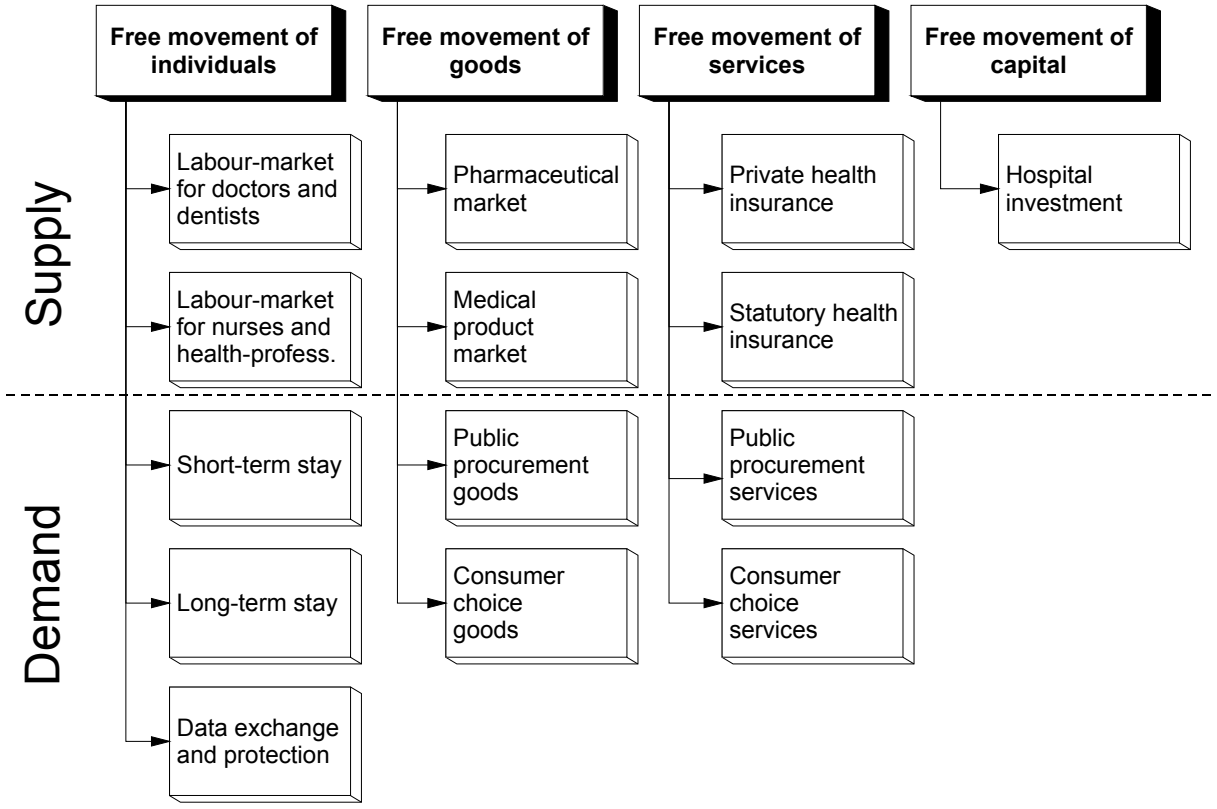


Fig. 3: The four freedoms and the categories defined to analyse the interface between SEM integration and health services

## 4. Research strategies and methods used in Phase 1

This study explored virgin territory as far as its empirical data were concerned. This meant that no existing databases or systems of categories could be utilised. European interventions had to satisfy two criteria in order to be included in the analysis:

1. the structures for regulating, financing or delivering medical care in the health service had to be clearly defined; and
2. the regulatory measure had to be clearly attributable to the SEM and thus to one of the "four freedoms".

At the European level, a research strategy consisting of several steps was applied in order to identify the relevant interventions:

- perusing the academic literature;
- perusing Commission documents;
- searching the internal database of the ECJ;
- systematically tracing back relevant references in documents already found.

These activities were accompanied by less systematic research which was either limited to certain subject areas or certain periods of time:

- a manual search in the Official Journal of the European Community, concentrating on periods where we assumed we would find documents which were relevant;
- searching the Internet database of the ECJ: http://europa.eu.int/cj/de/jurisp/index.htm (only contains decisions as from 17 June 1997);
- searching according to search criteria on the Internet pages of the EU server: http://europa.eu.int/index.htm.

Finally, the material was arranged according to the defined categories and sent to experts in those areas who were asked about the comprehensiveness of the interventions found and invited to amend the lists. The numerous tips received from colleagues as to which documents could be relevant cannot be underestimated. The analysis of these data was largely quantitative. It addressed questions in regard to the number of interventions, the dynamic of interventions, the number by instrument, the number of interventions by category etc.

In order to fulfil objective 2 (measures introduced in Member States to implement the relevant EU regulations, whether at national or regional level) specific investigations were carried out in each of the four Member States to capitalise upon the particular databases, information sources and networks available in each. For this purpose, the legislative or administrative acts on the national and regional level were collected as far as possible and available.

The data were then analysed quantitatively and qualitatively by asking questions such as following: Are directives transposed or not at national level? How long does this take? What (if any) is the difference between the content and scope of European legislation and the regulations formulated at national, regional and/or local levels to implement it?

## 5. Research strategies and methods used in Phase 2

This second phase was intended to assess the actual outcome and to formulate explanations for any differences and variations. Therefore, the following questions were posed:

- Does an intervention have intended and/ or unintended effects, and if so, at what level and in which way?
- Where and how does an intervention influence outcomes (range, quantity and quality of services; or equitable distribution of access)?

Research strategies and methods varied depending on the topic. The methods included interviews, focus discussion groups, surveys, analysis of documents and published literature etc. In order to produce a robust interpretation of the research data, a review mechanism was put in place for the studies. To this end, national experts were asked to assess the validity of the research findings and to identify further or other effects and associated expectations.

## 6. Research strategies and methods used in Phase 3

This final phase aimed at setting out the consequences of *alternative scenarios* using the appropriate methodologies. The effect of changes in EU policy was traced and predicted, and likely outcomes at Members States level forecasted. Scenarios are compilations of trends into differing images of the future. As such they are a tool for considering how interacting sets of trends might lead to a range of conditions in the future (Bezold & Hancock 1993; Garrett 1999).

Scenarios can be developed in a number of ways and with varying degrees of detail. Most often a "base scenario" is formulated which is an extrapolation of current trends. This is then contrasted with a number of alternative scenarios that might represent a more optimistic and a more pessimistic extrapolation. The main underlying strand is that the scenarios must be plausible, yet at the same time they should challenge current thinking. This is an important function of scenarios i.e. pushing the boundaries of orthodoxy and stimulating creative approaches to issues and problems.

First, scenarios in health can be based on a contextual analysis and this type of scenario considers large social, political and economic environments within which health is situated. Often some sort of visioning exercise takes place in order to formulate a long-range scenario with transformative characteristics, and this will be contrasted with a set of alternatives. These sorts of scenarios depend on multi-disciplinary research and the analysis of wide-ranging empirical data.

The second type of scenario is focused upon answering a specific question, most commonly associated with treatments of diseases or interventions aimed at specific sub-populations. The Dutch Steering Group on Future Health Scenarios uses this type, and their scenarios have included diabetes, ageing and cancer. These scenarios are based upon complex research, including detailed analysis of large data sets on mortality and morbidity, health technology assessments, Delphi techniques or other consensus methods.

The third type of scenario is an analytical exercise whereby various kinds of theory (e.g. social, political, economic or organisational) are tested by modelling predictions. These predictions can then be tested to different degrees: observationally and naturalistically (Sheaff 1999) using empirical research methods, or through focused analytical discussions in expert groups.

The scenarios developed in this project can be grouped under the type 3 scenario, specifically the scenarios developed through expert discussions. The rationale behind this methodological choice has been primarily pragmatic: the resources (time and money) for the project were insufficient to conduct type 1 or type 2 scenarios. By carefully selecting national experts in the fields under investigation, it was possible to organise structured workshop discussions, using the country reports and other relevant documentation, were held in order to formulate base scenarios and alternatives.

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