The European Union and health services: Summary

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1. Introduction

This book presents the results and conclusions from a project financed by the European Commission's BIOMED2 programme. The purpose of the project was to analyse the impact of the Single European Market (SEM) on the regulating, financing and delivery of health services in the Member States.

The Treaty Establishing the European Community (TEC) defines several areas of competence for the European Union with potential impact on healthcare and health services. In addition to the establishment of the SEM, these include competition law, agriculture, social protection, environmental policy etc. This book is concerned only with the SEM, with its four freedoms for persons, goods, services and capital.

The project has been organised in three phases, to meet the following six 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.

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.

2. Main issues and conclusions

2.1 Context and overall significance

- In political terms, there appears to be a contradiction between the purpose of the Single European Market (SEM) and the manner in which statements in article 152 of the Treaty Establishing the European Community are widely interpreted ("… excluding any harmonisation of the laws and regulations of the Member States. … Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.").
- This study investigated the impact of SEM regulations and directives as well as respective European Court of Justice (ECJ) rulings – taken together as "interventions" – on the health services of the Member States. It demonstrates that the relationship between health services as a major sector of Member States' economies and the SEM are intertwined in such a complex manner that it is virtually impossible to separate them. The argument, therefore, that subsidiarity applies to health services is not fully sustainable within the context of the SEM.
- Thus, the SEM may rightfully be seen as a challenge for health services, adding a further complexity to the principal driving forces such as changing healthcare needs, increasing patient expectations, the development of e-health, a regionalization of political decision making in a context of economic globalization. This is particularly true because the SEM inevitably regards the patient as an individual consumer rather than as a citizen with collective rights and responsibilities.

2.2 Markets and the European social model

- At a European level, the SEM requires health services to adapt to market rules, while at national level, governments seek to adapt market rules to ensure the effective delivery of health services within a social model.
- Differing views on the future structure of health services in Europe underlie much of the debate on health in Europe. These differences are based on two principal, divergent models – the European social model and market forces.
- SEM regulations and directives, while stressing the market, have not been exclusively aimed at achieving economic objectives – indeed some SEM interventions have a social purpose in terms of consumer and health protection (such as Directive 93/42/EEC on medical devices). Some directives are, arguably, even geared to regulating or limiting market forces (for example Directive 89/105/EEC on pharmaceutical price control and regulation). Nevertheless, there is a need to recognise that market forces and the European social model have differing objectives.

2.3 Intended and unintended effects

- SEM interventions have both intended effects (principally to create a single market with free movement of goods, services, people and capital) as well as unintended effects.
- Intended effects include providing the basis for a range of European activities in healthcare, e.g. a common public procurement system for goods and services, Europe-wide mobility of doctors and nurses, a common system for regulating medical devices, common licensing and market access procedure for pharmaceuticals as well as a European system to provide health services for tourists, and provisions to ensure healthcare coverage for persons working in other EU Member States.

- Unintended effects on the purchasing, supply and delivery of health services often result from the fact that these have not been sufficiently taken into account when the regulations and directives were drafted. For example, SEM interventions have sometimes led to increased health service bureaucracy. Small and medium-sized enterprises were also effected negatively by such requirements. SEM interventions may also lead to patient/citizen movements from one country to another in order to obtain treatment, thus undermining attempts at priority setting within the publicly-funded systems of member-states. Movement of doctors and other professionals may create shortages in poorer – especially accession – countries.
- The different political or organisational settings of health services, as well as countries' geographical settings within the EU, may lead to differing effects of SEM interventions within Member States. Policy-makers (and judges) should be aware such of differences.

2.4 Impact on health services

- While the actual impact of some SEM regulations, directives and ECJ rulings on health services may currently be marginal, the inherent conflicts behind many of the directives and ECJ rulings may have a significant impact and may cause unexpected systems turbulence.
- For example, should the cases which are currently pending at the ECJ be decided in favour of free choice of healthcare goods and services, then the patient-provider relationship would be more firmly embedded in the range of European activities in healthcare – with free choice of provider dominating other objectives. Should such free choice be permitted across national borders, it might also have to be mandated within countries – with potentially major consequences for healthcare systems.
- The thrust of such policy is to emphasise individual rights as opposed to the collective priorities (and collective rights) of public healthcare systems. While it is generally the better-off who can currently take advantage of such individual rights, the extension of free choice to healthcare within Member States would make the benefits more widely available. On the other hand, collective priorities may be undermined by mobility which prevents effective national planning. Basic characteristics of Beveridge (NHS) systems in particular may be threatened.
- Assuming that there is a triangular relationship between citizens/patients, third party payers, and providers (Figure 1), we can see that provider-citizen/patient and the provider-payer relationships (i.e. the supply side) have been the subject of the majority of SEM interventions (especially if competition laws are also taken into account).

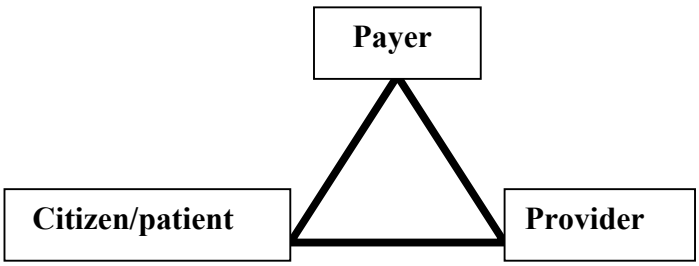

Fig. 1: The triangular relationship between citizen/ patient, third-party payer and provider

- The relationship between citizens/ patients and third-party payers – the third side of the triangle – has not been subject to either EU regulation or ECJ rulings. This might entail, for example, either regulating citizen choice of third party payer or developing a European benefits package. If either of these were to lead to a market of third-party

payers, it would constitute a powerful driver towards a European system of health services. However, such a development would certainly lead to substantial systems turbulence, again particularly in Beveridge systems, and would almost certainly be resisted by Member States.

2.5 Implications for policy

- Based on the future scenarios conducted as part of the study, neither total integration of health services at a European level nor the exclusion of health services from the SEM are probable. The third option, "muddling through", does not provide easy solutions, but doing nothing is not a sensible option.
- An honest and explicit debate on the advantages and disadvantages of "muddling through" must take place. This first requires an acceptance of the intertwining between the SEM and health services. Such an acceptance would enable the development of a proactive role for health policy-making – as opposed to the current decision-making which is all too often reactive, especially to ECJ rulings. While different objectives and interests will no doubt continue to be the subject of compromise, an overt healthcare strategy to manage the relationship between the SEM and healthcare should be developed.
- There is a need to continue to monitor the effects of the SEM on health services. This should be combined with the health information strand of the new EU health strategy.

2.6 A note on globalisation

- While this project focuses primarily on the SEM, it should not be forgotten that health services – as part of the SEM – function within a global market in which the demand for health professionals and the market for health products operates. The World Trade Organization is increasingly active in this area, and Member States will have to reconcile national interests with the European Commission's right to negotiate on their behalf (Article 133 TEC).
- The SEM is part of Europe's strategy to compete in the world global market place. The EU and its Member States should develop a strategy which would include its social objectives as part of this externally-oriented policy – emphasising a sustainable European social model alongside the Single European Market.

3. Background and methodology

3.1 Context and overall significance: the Treaty, the SEM and health services

According to Article 3 of the Treaty establishing the European Community, the European Union has, in principle, a broad policy mandate for health ("… the activities of the Community shall include … a contribution to the attainment of a high level of health protection …") including specific tasks which are set out in Article 152 and other articles. Nevertheless, according to the principle of subsidiarity and the widespread (but disputed) political interpretation of Article 152, the organisation and delivery of health services are argued to be excluded from this policy mandate.

The assumption, however, that European economic integration is separated from the purely national responsibilities for healthcare – which most commentators as well as policy makers have accepted as the reality – has to be questioned. Since a healthcare system is not

only a part of the welfare state, but at the same time an important part of the economy, it is impossible to regulate one without causing effects on the other. Restricting health systems policy to the Member States while sponsoring economic integration at EU level does not create a tidy or even meaningful separation. Free movement of persons, goods, services and capital also means free movement of physicians, nurses, other professionals, patients, drugs, medical technology and healthcare services. The relationship between the European Union – including the Single European Market (SEM) – and the health systems and services of Member States is therefore becoming an increasingly complex area.

There have been different interpretations of the SEM. Clearly it is an "economy wide" initiative, not specific to social welfare let alone health. Accordingly, EU policy may have an effect upon these services mainly through generic, i.e. sector-unspecific, regulations. Some have portrayed the SEM as an attempt to regulate the (otherwise) free market, at least in part to ensure the protection of social objectives and social values. Others have tended to see it simply as a tool of economic policy. Even here, however, debate exists between those who see the SEM as a means of promoting competition both across the European Union and even within Member States, and those who see it as a means of allowing rationalisation and concentration (merger into large scale industrial sectors) against a background of globalisation. These debates provide an important context for understanding how SEM interventions might affect health services, and for determining whether or not the impact of these interventions was intentional or accidental.

It should be remembered that health policy exists in a wider environment, both within Member States or across the European Union. Health policy is concerned with the effective provision of a health service as part of the welfare state objectives. Health policy must also take into account the contribution of health and the healthcare industry to the economy as a whole. "Healthier workers" and workers employed in the health industry – as well as its profits – are the concern of most governments.

3.2 The project's methodology and terminology

The project's research has concentrated on the four freedoms of the SEM, i.e. the free movement of individuals; the free movement of goods; the free movement of services; and the free movement of capital. To explore their effects on health services, relevant categories were defined, taking both "supply" and "demand" factors into account (Figure 2). 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 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 (= SEM regulations and directives as well as respective ECJ rulings). 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.

In summary, Figure 2 presents a typology devised to explore relevant legislation and issues. This typology is not the only possible way of organising the study, but is a robust means of reflecting on the impact of the SEM on health services.

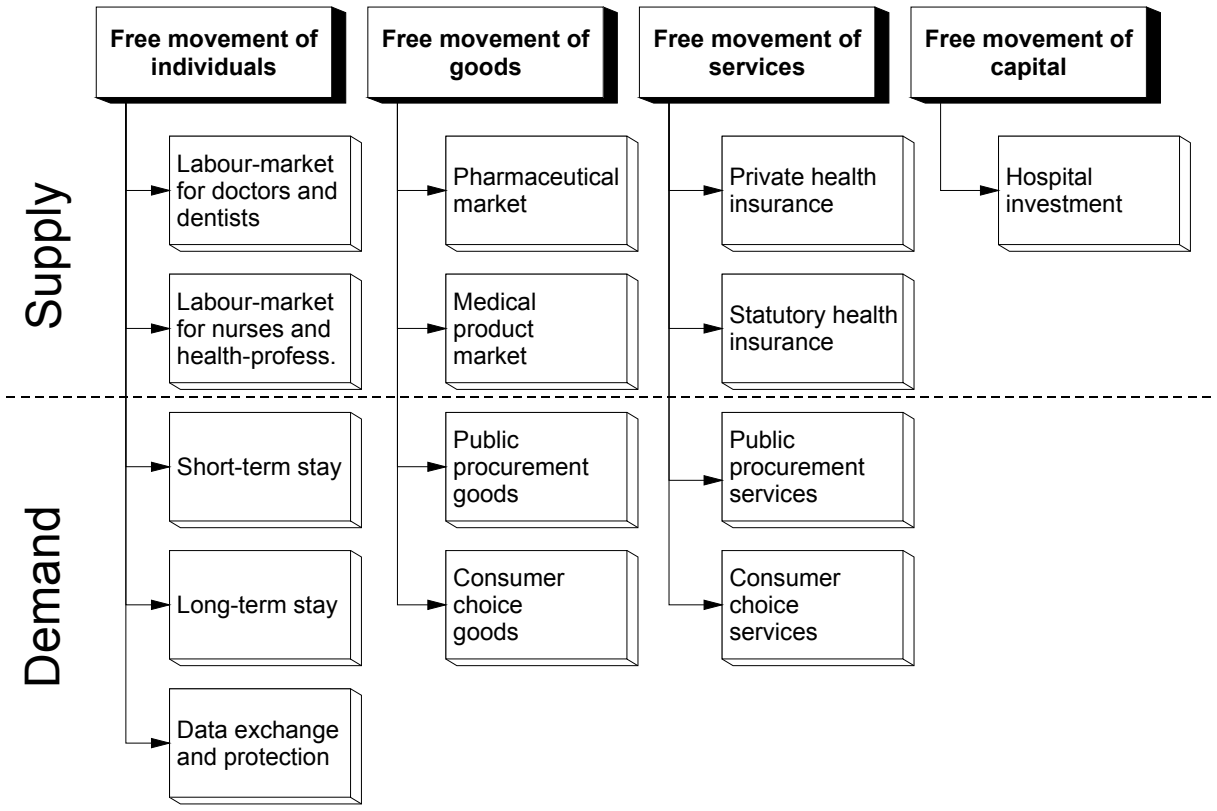

Fig. 2: Analytical categories used in the project

The categories of Figure 2 are not all treated equally in the project. The case studies and scenarios concern some but not all of the categories in Figure 2. The case studies have produced analyses of the impact of interventions on specific areas which 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 has been led by one of the national project teams and focuses on the issues that are of particular relevance to that 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.

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.

A distinction is made between the impact of SEM interventions and outcomes in terms of effects on health services or healthcare. 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 of enthusiasm for Europe ("being a good European"); an "automatic" process of transposition of regulations; or the perception that regulations offer national advantage.

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.

For each of the four countries, reports are available of the transposition of key directives (based on the application of the "four freedoms" to health services). 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

Outcome refers to the effect of SEM interventions on health services and healthcare – in terms of management, finance, supply and delivery. Effects may be intended or unintended. The case studies and analyses pay particular attention to these effects and to the different perspectives of the EU and the Member States.

4. Main findings

4.1 SEM interventions referring to health services

The collection and analysis of all SEM interventions referring to health services (with potential impact on regulating, financing and/ or delivery of health services in the Member States) revealed that

- the European dimension in health services began directly with the formation of the EEC in 1958;
- the frequency of interventions relevant to health services has increased since the 1970s in particularly, and especially in the first half of the 1990s;
- in total, 233 regulations, directives, decisions, recommendations and rulings, which met the project's criteria, were issued between 1958 and June 1998;
- almost two thirds of these interventions emanate from European political decision-making process, but more than one third result from the judicial process at the European Court of Justice;
- the interventions which, potentially, have the most significant effects on the health systems of Member States are usually based on the more powerful instruments – directives and proceedings for preliminary rulings; and
- the distribution of interventions among the four freedoms is uneven with the vast majority focusing on the free movement of persons and goods. Approximately two thirds of the interventions are concerned with the supply-side rather than with the demand-side.

4.2 Labour market for doctors and nurses

Current EU policy on the free movement of labour requires that healthcare workers, who are EU citizens and meet certain training criteria, have the right to register to practice in Member States other than the one in which they trained. The case study focused on the movement into the UK of doctors from the EEA (European Economic Area). The reasons for European mobility are a result either of "push" factors (medical unemployment or lack of specialist training posts in the "home" country) or "pull" factors (the reputation of UK education attracting trainees).

Formally, there is mutual recognition of qualifications between Member States. However, at the informal level, there is considerable uncertainty expressed as to the content, comparability, and quality of the medical (and nursing) curricula of various countries. This affects assessment of doctors' suitability for training posts, which can result in inequality of training opportunity.

In addition, varying demarcations between the organisation of clinical specialties in different Member States may mean that it is difficult for a doctor from another Member State to find an appropriate position in the UK NHS. The "general physician's" work may have a different content in one country as compared to another. EU wide policies and directives are in place and have been transposed in the UK; yet their interpretation and implementation is variable – not only because of national "selfishness" but also because of genuine discrepancies in quality and suitability.

Scenarios for the future demonstrate that increased mobility may adversely effect the supply of medical personnel in the poorer countries of the European Union – especially accession states when they become full members. There may be a "perverse incentive" to rely on imports of doctors rather than educating and training adequate numbers (at undergraduate and postgraduate levels) in the home country.

Against this can be set the view that mobility will always be limited for cultural, linguistic and other reasons. Member States will continue to seek "national self sufficiency" in healthcare personnel, although the effects of the SEM, in terms of the free movement of doctors and nurses in particular, will continue to be felt, if only at the margin.

4.3 Pharmaceutical market and medical product market

These topics were explored with particular reference to Sweden. As well as the Treaty of Rome's general stipulation of free trade in goods, there are a number of specific directives aimed at facilitating single markets for pharmaceutical products and medical devices. Swedish domestic legislation closely follows directives from the European Commission and judgements from the European Court of Justice.

The EU legislative framework has mainly been concerned with the approval procedures, patent protections, standards for distribution and marketing, and with less influence on price regulations and the design of reimbursement and drug benefit systems. The centralized EU approval procedure, and co-operation between national regulatory authorities have increased the capacity of these agencies to deal with the growing complexity of the approval process for new chemical entities. By co-operating and sharing information and knowledge about the same new products, these regulatory authorities are on par with (or at least less inferior than) the multinational pharmaceutical industry. Supra-national regulation can thus be seen to increase capacity to deal with the multi-national pharmaceutical industry. Another important consequence is that the centralized approval procedure leads to a clear separation of the decision to approve a new drug and the decision to subsidize it.

A set of EU-decisions (directives about standardized packages, the ECJ verdict on parallel imports) has clearly facilitated the development of parallel importation of drugs – drugs sold more cheaply abroad that can then be re-imported to the country of production to "undercut" the existing supply.

The results from the Swedish case study demonstrate that most EU directives and regulations concerning the pharmaceutical market have had influence on the supply side rather than the demand side (where questions of pricing, subsidies, availability of drugs, and services are regarded as national issues).

Regarding medical devices, it appears that larger companies have found it easier both to adapt to requirements of the directives and to derive benefit from the EU stamp of approval. For smaller companies, which did not have ambitions to develop exports, the directives have created problems but few benefits. While there has been general recognition of the benefits of common standards, smaller companies have also had greater difficulty and cost in standardising for sale outside their own country. Users have also had difficulty in influencing design and standards.

EU directives have also had an impact on medical technicians. The broader definition of medical-technical products has had the effect that medical technicians are now responsible for a larger area of responsibility. There are, currently, discussions within the profession concerning the responsibility for the repair and maintenance of medical-technical products.

An unintended outcome of Directive 93/42/EEC (which specifies the requirements and regulations for testing, certification and labelling of appliances and equipment) concerns the obligation to report serious adverse events. However, many countries within the European Union do not have national laws requiring users to report adverse events. The study indicates that accident reporting systems within the EU may not work sufficiently well unless the Swedish National Board of Health and Welfare (or the corresponding authority in other Member States) demands that users of medical products are obliged to report either accidents or narrow escapes both to the manufacturer and the supervisory authority.

An additional problem identified in the study is that ethical committees in the respective countries who evaluate applications for the commencement of clinical testing command varying degrees of knowledge and competency. This can therefore lead to significant variations in evaluations of applications for clinical testing. This weakness does not appear to have been sufficiently recognised.

4.4 Public procurement

This case study was carried out in Spain, and concerned the public procurement procedure in the Andalusian health service. The European Directive on public procurement is geared to developing a Europe-wide internal market. Public procurement, however, also has a potential influence on the evolution of the industrial and commercial structure of any Member State, and the European Directive on public procurement has clearly led to substantial changes in Spain.

The study detected an increase in the volume of purchases made using the method of official submission (calls for tender), with approximately 67 % of the total expenditure on public procurement of goods occurring through calls for tender in 1998. More than 89 % of these submissions were advertised in the official journal of the European Community.

On the positive side, the new legislation has led to an improved organisation of services and greater objectivity in specification. On the negative side, purchasing has become more bureaucratic; it takes longer to make a purchase; and large and multinational companies can adapt themselves more easily than small and medium enterprises (SMEs) to the

requirements of the European legislation. There may also be perverse incentives to "break down" procurement into units smaller than the level at which European wide calls for tender must be made, in order to avoid the bureaucracy involved in a Europe-wide tender.

The study came to the conclusion the public procurement directive fails to take adequate account either of the specific nature of the health sector or of the EU's objective to create sustainable SMEs.

NB: In regard to public procurement in healthcare it is important to note that the project concentrated on applying public procurement rules by healthcare providers such as hospitals and not applying them to health services themselves, i.e. making them the subject of procurement by the public payer. This discussion has started recently in Sweden after St. Göran's hospital in Stockholm was sold to a private for-profit company – with the agreement calling for a procurement process of hospital services in Stockholm from 2004.

4.5 Consumer choice for healthcare goods and services

Regulation EEC1408/71 – which serves to coordinate social protection systems in the European Union to allow the free mobility of workers and citizens – also provides the basis for facilitating rather than restricting cross-border consumer choice of healthcare goods and services. It could even be argued that the ECJ's Decker and Kohl rulings, which made the free movement of goods and services applicable to social protection schemes, may not have been necessary if reimbursement procedures had been handled in line with this regulation.

The project identified four dimensions to consumer choice: i) access to the widest possible range of services; ii) access with fewest possible restrictions (restrictions being authorisation procedures or mandated referral patterns); iii) the maximum choice of provider; and, iv) full reimbursement for any amount charged by the provider. (It may of course be desirable to restrict some of them in pursuit of other social objectives such as equity.)

Potentially the impact of European legislation and ECJ decisions on cross-border consumer choice is high, although the outcome to date has been very limited. Four factors account for the limited numbers of patients actually taking advantage of cross-border choice: i) restrictive handling of the E112 procedure whereby care abroad has to be pre-authorised; ii) differences in the "healthcare baskets" across Europe; iii) lack of cost reimbursement provisions in many countries; and, iv) the nature of medical goods themselves and their distribution. The political impact of the Kohll and Decker rulings, however, was substantial, since the ruling resulted in the much-debated method to enable cross-border care (in addition to E111 and E112), namely the ex-post patient reimbursement of unauthorised goods and services.

Germany (the location for this case study) provides an illustration that there is potential for cross border consumer choice in prescribed medical goods. During the brief period when German legislation allowed free use of patient reimbursement instead of the usual application of the benefit-in-kind principle, there were reports from sickness funds that bills from abroad had been cashed in. Additionally, a strong claim in favour of the cost reimbursement principle for the purchase of prescribed medical goods and services was made by old age pensioners living abroad for long periods who did not wish to give up their German residency.

The Court ruling in the Decker and Kohll cases was restricted to: 1) ambulatory care services which are 2) included in the benefits' catalogue of 3) patient reimbursement systems. Cases currently pending at the ECJ challenge these three restrictions. If decided in favour of increased choice, there will be significant implications for inpatient care and benefit-in-kind systems.

An unintended outcome of European interventions has therefore been the challenge to the benefit-in-kind principle. While this principle has been favoured in most Member States' health services in order to protect the consumer from direct payments, it tends to restrict the sovereignty of the patient in relation to cross-border consumer choice.

However, even if the ECJ decided against increased choice, i.e. in favour of a continuation of the status-quo, this would raise the question whether – within a SEM – it is justified that existing alternative methods of social protection institutionalise different methods to gain access to different benefits, partially different providers and potentially different levels of reimbursement.

Unrestricted access to services and providers outside the borders of the individual's country of insurance, reimbursed by public payers, would pose serious questions for national policy. How could Member States deny choice inside their own country (for example, to restrict access to a limited number of contracted providers) if these limitations do not exist for cross border care? To what extent would such a new situation undermine national health policy measures, such as rationing/prioritisation, or (more generally) cost-containment?

Under these circumstances, Member States might seek to restrict access to a defined minimum standard benefits package. Yet this would not provide a real solution to the problems raised by free mobility or patients, if this was only implemented by individual Member States, as access to nationally excluded services would be available for patients willing to travel. This leads to the ultimate question: would Member States have to design a uniform benefits catalogue, apply uniform reimbursement rates and a uniform system of accreditation, contracting and payment of providers – in effect a "European healthcare system"?

5. Further considerations

5.1 Markets and the European social model: the market ruling – or ruling the market?

Inherent in many of the conclusions emerging from this report is a critical difference between the way that the European Union views the relationship between "the market" and health services and the way that Member States view this relationship. At a European level, the SEM requires health services to adapt to market rules, while at national level, governments seek to adapt market rules to ensure the effective delivery of health services within a social model.

However, what is known as the "European social model" embraces particular values concerning social policy. The relevance of these values to health services – for example, promoting both solidarity and equity in access to health services – should be explored and stated openly. Where SEM regulations have consequences that may conflict with such values, it would be desirable to ensure that SEM regulations are not interpreted in a manner which will damage the values inherent in the "European social model".

Clearly where the freedoms embraced by the SEM are basic human freedoms (especially mobility of individuals), they cannot simply be ignored in the case of health services. To that extent, there is no question of simply "exempting health from the Single European Market". There may however be significant cases where regulation of the market is required in order to achieve health objectives. Paradoxically, this requires a new coherence and prominence for EU health policy – not just to draw a sustainable rather than accidental line between Member State policy and EU-wide policy, but also to make the aspirations of both these actors more coherent.

5.2 Avoiding possible unintended SEM effects in the future

It is not the function of this report to trace potential unintended effects to their extremes. It is worth pointing out, however, that the basic policy choice at European level concerns how best to resolve the inherent conflicts between the SEM and health policy. Is continuing pragmatism enough? Or will it be necessary to develop an EU health policy so that the SEM avoids negative effects either in relation to equity or solidarity in public healthcare systems, on in relation to perverse incentives as regards the education, training and movement of individuals (workers and consumers).

A coordinated approach would facilitate an exploration of options and possibilities to avoid the following unintended effects which otherwise might occur:

- *Restriction of benefits?* It is conceivable that future decisions of the ECJ in favour of increased choice might motivate or force the European Union and/or Member States to move towards a "standard benefits package". This might occur in a manner to threaten comprehensive public coverage if done in a "political panic".
- *Privatisation of supply?* Emphasising individual rights (e.g. to mobility) over public objectives is likely to increase the role of the private sector, since public planning is less viable when factors of production and rules of consumption cannot be controlled. Yet increasing reliance on the private sector to correct imbalances or shortages of health personnel or facilities might be at the expense of equitable access to publicly funded healthcare systems. The accession states in Central and Eastern Europe might, for example, experience a shortage of doctors over time due to emigration (partly due to SEM freedom of mobility) to richer Member States of the European Union. The consequence would be increasingly private medical education to produce doctors for private suppliers of healthcare, and this healthcare would disproportionately be purchased privately by the better off. Medical students would only enrol if they had expectation of income adequate to pay off their loans – probably private healthcare.

  Affordability of public healthcare in poorer Member States would be called into question if there were a need to pay "market rates" for scarce doctors, nurses and other healthcare professionals. Additionally, the mobility of scarce professionals may have an unintended incentive in the light of the EU's social objectives: Member States have a disincentive to educate doctors and other professionals publicly if a significant number are likely to emigrate.
- *Concentration of companies:* The SEM may incorporate contradictory objectives – first, competition within Europe; but second, the competitiveness of Europe in the world.

  On the one hand, it is often the case that European Union policy is aimed at the promotion of competition both within Europe and within the Member States and, indeed, the promotion of Small and Medium Enterprises (SMEs). But it is clear, particularly from the public procurement study, that competition within Europe may damage SMEs to the ultimate detriment of health services.

  On the other hand, regulations start from the recognition of increasing concentration not only in European but also in global markets. European-level recognition of new drugs through the EMEA can, for example, be a means of streamlining in the context of a multinational market for pharmaceuticals. The European Union's logical intention to use the SEM to strengthen its competitive position in the global marketplace can lead to concentrations of companies which might have negative consequences for health services.

5.3 The future for health policy-making: driving or being driven?

Even if the impact of many SEM interventions is small in terms of numbers of patients or professionals affected by these interventions, the systems turbulence caused by these interventions, particularly those resulting from ECJ decisions, may be greater than the numbers involved. SEM directives and ECJ rulings have the potential – in a "worst case" scenario – to undermine Beveridge systems if "managed competition" in compliance with other aspects of European law leads to the spread of sickness funds in the context of the insurance model. Equally, there could be considerable turbulence in Bismarckian systems if the rules were to be changed away from a "social" health insurance model.

To address such problems, arising from the unintended consequences of European Union regulation on health services, it is therefore time to raise the profile of health policy at the European Union level – but in a manner consistent with the aspirations of Member States.