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

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EXECUTIVE SUMMARY

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

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

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

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

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

Nevertheless, many individual elements of health care are, entirely reasonably, subject to market principles. Governments generally do not produce or distribute pharmaceuticals. Health facilities purchase equipment, whether clinical or otherwise, on the free market. Both medical equipment and technology are freely traded on the international market. Many health professionals are self-employed, engaging in contracts with health authorities or funds. Patients may obtain treatment outside the statutory health care system, either in their own country or abroad. All of these matters are entirely legitimate subjects for applications of the internal market; indeed the
fundamental freedoms enshrined in the Treaty require that such transactions are transparent and non-discriminatory. Furthermore, to the extent that reforms of health systems adopt market mechanisms, they indirectly become exposed to the scrutiny of European law.

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

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

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

Even if the ECJ considered that requiring prior authorisation in all cases in which health care is delivered in another Member State constitutes a barrier to free movement of services and goods, it accepted in the Smits-Peerbooms cases that it was a necessary and reasonable measure to guarantee a balanced and accessible supply of hospital services. However, the Court would only accept such an exemption to the principle of free movement of services if the criteria applied to grant the authorisation were objective and non-discriminatory vis-à-vis providers established in another Member State. In that respect, it found the Dutch authorisation conditions not to be compatible with the principle of equal treatment, because they are likely to favour Dutch providers.
While not completely outlawing the use of a prior authorisation system, the Court rulings have radically restricted Member States’ discretion to determine their own policies by requiring that their decisions are necessary, proportional and based on objective and non-discriminatory criteria. Furthermore, in the Vanbraekel ruling, the ECJ considered that if authorisation is given - or is wrongly refused - the patient should be granted the best possible reimbursement tariff, either that of the home country or that of the providing state. By linking the Regulation 1408/71, on which cover for health care abroad has been traditionally based, with the free provision of services, the ECJ seems to have created difficulties for this system of co-ordination system.

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

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

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

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

The pharmaceutical sector creates numerous difficulties as the international dimension is so much greater and the challenge of balancing trade and health policy concerns is especially acute. One example is direct to consumer advertising where there is strong commercial pressure to permit it but sound health policy reasons to reject it. The EU institutions have created a framework in which the supply of medicines to a common or internal market has been harmonised along common lines to the benefit of drug manufacturers (and intermediate suppliers who source their products -parallel imports- from different markets within the EU) even in the face of intellectual
property rights. European law and policy has had much less direct impact on the demand side. Pricing and reimbursement controls as demand side management techniques are only marginally impacted on by EU law - whether primary treaty rules or secondary harmonising legislation. Proxy demand side controls on doctors' prescribing, wholesalers and pharmacists margins are outside the remit of EU pharmaceutical policies. However, e-health and e-commerce could provide many possibilities to break down the traditional single gatekeeper model of access, allowing multiple entry points and the direct distribution of information (of whatever quality) to patients. Whether this will allow the Commission to influence proxy demand and demand more directly remains to be seen.

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

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

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

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

There are several ways in which activities may qualify as non-economic. They may be sovereign, in other words necessarily performed by the State when exercising official authority. However, the State must show that it is necessary for it to perform this activity, and must exercise caution when delegating its role to other bodies. It may be a social activity, but here it must demonstrate that it involves social protection and is based on the principle of solidarity. It may also be exempt because it involves no identifiable payment or because the activity simply involves the organisation concerned meeting its basic needs to continue to function. However, it is easy to see
how poorly considered health care reforms, especially where they introduce market-mechanisms and decentralisation, might render organisations unexpectedly subject to competition law.

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

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

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

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

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

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

So what is to be done? This report makes the case for an explicit European health policy, that would bring considerable benefits, setting out an agreed position among Member States on what they are seeking to achieve through their health care systems. There is likely to be sufficient
agreement to reach a common position, at least at the level of principles. Consequently, if the European social model is not to be undermined inadvertently by the inappropriate application of EU law designed to meet needs in other sectors or a piecemeal series of judgements on health care, it will be necessary to agree on a statement of fundamental principles that enshrine the goals of European health systems, that balance the internal market with social goals, and that can be incorporated in a future Treaty.

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

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

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

These procedures will, however, take time and it is apparent that action is needed now. Consequently, it is of the utmost importance that the EU establish, as soon as possible, a system that can monitor the impact of EU law on health care systems on a continuing basis.
CHAPTER 1: A EUROPEAN SOCIAL MODEL?

Background

Health care policy in the European Union has, at its centre, a fundamental contradiction. On the one hand, recent Treaties, which are the definitive statements on the scope of European law, state explicitly that health care is a responsibility for Member States. On the other hand, as health systems involve interactions with people (staff and patients), goods (pharmaceuticals and devices) and services (health care funders and providers), all of whose freedom to move across borders is guaranteed by the same Treaty, it is increasingly apparent that many of their activities are subject to European law. Yet the picture is far from straightforward. The European Union (EU) has both economic and social goals and, since the Treaty of Maastricht, it has been required to “contribute to the attainment of a high level of health protection”.

But Member States, reflecting the societal preferences of their citizens, have chosen different ways to organise their health care systems. These reflect many factors. The overall design often reflects history, so commonly accepted norms are important. For example, social insurance systems require an existing set of relationships between employers, trade unions and government. National health services imply a different relationship between the individual and the state, in which the social partners play a less prominent role. Levels of funding reflect views about the balance between individual and collective financing of health services, as well as the amount of redistribution that is desirable. Methods of provision reflect views on the balance between professional and organisational autonomy on the one hand and the role of the state in ensuring effective treatment and an equitable distribution of facilities. The ways in which these varying goals are achieved reflects views about the legitimacy of regulation, incentives, or other levers. These decisions have combined in ways that mean that, while they are often thought of as falling within broad categories, each national health care system in Europe is unique. Furthermore, given their grounding in national culture, institutional frameworks, and contemporary political choices, there is no obvious reason to seek to harmonise them. Indeed, any attempt to do so would almost certainly end in failure, as well as potentially provoking widespread popular dissent.

For these reasons, the application of a uniform legal framework, as set out in the EU Treaties, will inevitably be problematic. But the challenge is even greater. Achievement of the single market, through the promotion of free movement, must proceed but where policies have implications for national health care systems, legislators and the European Court have no framework of reference with which to work, other than general statements about ensuring high levels of health protection.

This report will argue that such a framework is needed. By exploring the evolution of European law on movement of patients and professionals, pharmaceuticals and medical devices, insurers and health care providers, it will show that the existing situation has created uncertainty and, in places, confusion. Health care policy makers are frequently forced to speculate about the application of European law to their actions on the basis of judgements made in other sectors, or in systems whose relevance to their own is far from clear. This creates the worst of all worlds; the potential benefits that the single market might bring are not realised and the unintended consequences of laws drafted to achieve a quite different objective may impair the ability to provide effective services.

The remainder of this chapter will explore the extent to which there is consensus on the goals of health care in Europe. In other words, might it be possible to produce a fundamental statement about what they seek to achieve?
The development of a European social model

Any attempt to define a European social model must start by differentiating it from potential alternative models. On the assumption that models implemented in developing or middle income countries are of limited relevance to this discussion, the most obvious comparator is that of the USA. As the remainder of this section will show, its approach to social policy differs greatly from that seen in Europe, in many different ways, but one simple comparison suffices to illustrate the fundamental nature of this difference. While all European countries have ensured universal, or near universal health care coverage for their populations, the USA has singularly failed to do so. In this way it stands apart from all advanced industrialised nations. Others outside Europe, such as Japan, Australia and Canada, stand with Europe on this fundamental issue.

But is this sufficient to define a specific European model. And if so, where do the boundaries of this model lie, and by extension, where might consensus on the goals of the health care system be reached?

To answer these questions it is necessary to look to history. A concern by the state for the health of its population is relatively recent, emerging identifiably in the nineteenth century. By the end of that century welfare states were beginning to spread across Europe. The spread of health care coverage was, however, slow, beginning with coverage of industrial workers in Germany in the second half in the eighteenth century and only including agricultural workers in some countries in the 1960s. (1) This pattern was related intimately to the process of industrialisation. Industrialisation, and the consequent division of labour, changed the social structure fundamentally. (2) Existing social support systems, based on relationships within families and local communities in agrarian societies, were replaced by new systems of inter-dependence that met the needs of the many individuals who found themselves in unfamiliar and often hostile settings in the newly industrialised towns and cities. And their needs were often great, as is apparent from evidence of worsening of the already poor health of the English working class in the late 19th century. (3)

It soon became clear that a response by the state was required to address these new needs. From an economic perspective, health care was a public good; under normal market conditions an insufficient amount was produced. Those whose need was greatest did not have the purchasing power to create effective demand, so that illness reduced productivity, and thus earnings of employers, and the state was unable to draw on a sufficient healthy pool of manpower in the event of war. It was subject to externalities; the middle classes had an interest in ensuring that they did not contract disease from freely roaming fever victims and were not murdered by those with psychiatric illnesses, although some were also motivated by altruism.(4)

Importantly, these factors were much less important in North America, and in particular in the USA. Under-performing workers could always be replaced by the continuing tide of immigrants from Europe, with the barriers placed in their way acting to select only the fittest (with the health examinations on Ellis Island the most explicit of these). And unlike the relatively crowded countries of north-western Europe, the USA had what seemed to be almost unlimited space, so that the middle classes could isolate themselves from the poor by distance, a phenomenon illustrated graphically by the film “The Great Gatsby”, where the rich insulated themselves in their mansions on Long Island.

The next major extension of the welfare state in Europe came after the Second World War. One major factor was the shared experience that had affected entire populations but attitudes were also shaped by the reaction to the social forces that had given birth to extremism, which in turn had contributed substantially to the war. Once again, North America did not share directly in
these experiences. The collective trauma of the depression of the 1930s might have led to universal coverage; indeed there was considerable enthusiasm for it among both the public and medical profession. However, a small group of predominantly urban doctors within the American Medical Association were able to block reform until 1938, by which time Roosevelt’s efforts were focused on foreign affairs and the political make-up of Congress had become unfavourable to social reform. (5)

It was not until 1965 that another Democrat President was able to introduce a limited extension of coverage, again in the face of sustained opposition from the medical profession.(6) Canada, which shared many of the historical experiences of the USA, only achieved universal coverage in 1972.

In the space available it is not possible to engage in a detailed comparison of the wide range of health care systems that exist in Europe, which anyway have been described in detail elsewhere. Instead, the remainder of this section will explore the extent to which they share common features.

As is apparent from the preceding discussion, the fundamental distinguishing feature of European health care systems is the provision of near universal coverage. The precise nature of entitlement varies. In countries with a single national health system funded from taxation, entitlement is usually straightforward, based on residence within the country in question. In social insurance systems the situation is more complex, especially where there are multiple funds, but all Member States with such systems have made membership of a sickness fund compulsory, although a few countries have exempted the wealthy, assuming that they can make alternative arrangements. Governments may, however, require cover against catastrophic illness, as in The Netherlands. They have also made arrangements for those who would otherwise not be covered, although it must be recognised that these may be less than satisfactory for certain groups such as illegal migrants.

However the European social model goes beyond simple coverage, seeing social protection as a means of promoting both social cohesion and economic growth. To do so requires that the organisation of health systems promotes equitable access to effective care. Health systems should do more than simply meet expressed demand by individuals. Specifically they should actively assess the health needs of their populations, in particular those that are not being met, and ensure that effective policies are provided equitably to meet them.(7) The extent to which this approach has been implemented does vary but it is a clearly identifiable aspiration in all EU health care systems. One manifestation is the increasing interest in the concept of targets for health improvement. (8)

Other shared features of European health systems are more difficult to measure but can be implied from the arrangements put in place by Member States. Europe has not seen the growth of vast for-profit chains of health care providers or insurers seen in the USA. This appears to reflect a more fundamental belief, that health care is not simply a typical industrial concern. Many of the factors that led to the creation of the European welfare state in the 19th century, including the characteristic of health care as a public good and the existence of externalities, still apply, with others, such as the asymmetry of information between consumer and provider becoming even more important. This does not mean a rejection of market principles in the delivery of health care; it is apparent that some activities, such as the production and distribution of pharmaceuticals are best undertaken as a commercial activity, as are many other aspects of procurement of (non-clinical) services, but it does mean that Europeans are unwilling to go down the path taken by the USA. As this report will show, this creates difficulties when European law is being applied to activities that impact on the organisation of health care as nowhere in the treaty
are these principles enunciated in a way that would provide context for policies that seek to promote free movement of people, goods or services.

In summary, the main message of this section is that Europe's historical collective experience, and the consequent emergence of institutions and shared beliefs about the role of the state, differs fundamentally from that of North America. However it is important to know whether these factors remain applicable today. This will be explored in the next section.

**The European social model: popular acceptance**

Social policy is embedded in broader considerations about how people organise their lives. Thus, the USA has achieved a higher level of economic attainment (as measured by GDP) than Europe but has done so primarily by increasing the number of hours worked per year. Partly because of its lower investment in capital, labour productivity per hour worked is somewhat lower than in Europe. In other words, Europeans have, to some extent, chosen to trade income for leisure. (9) Europeans are also more willing to forego some degree of economic growth to ensure, through strict application of planning laws, the preservation of the environment. The USA has chosen a model that tolerates wide variations in income, while accepting (perhaps reluctantly) the social consequences such as high levels of violent crime. In contrast, all European governments, while maintaining minor differences according to their political complexion, have embraced the need to tackle social exclusion.

However, there is compelling evidence that, at least in the field of health care, the European model continues to have more widespread popular support in Europe than its American alternative has in the USA. Public opinion surveys undertaken in the 1970s showed that, among western European countries, approval for the performance of government in the provision of medical care exceeded that seen in the USA in all countries except Italy, with the other European countries included (Switzerland, Netherlands, Austria, Germany, Finland and United Kingdom) all recording approval ratings of over 70%. (10) A later survey, undertaken in 1990 in 10 industrialised countries, found the USA to have the lowest percentage of respondents stating that their health care system required only minor changes. (11) The USA also had the highest percentage of respondents who believed that their system needed to be completely rebuilt (29%).

A nascent neo-liberal political agenda in the 1980s began to challenge the prevailing view, in particular seeking to reduce the role of the state in areas such as health care. Such moves attracted little enthusiasm. A survey in all 15 EU countries in 1996 found, overall, that 84% of respondents across all countries favoured either the same or higher levels of expenditure, ranging from 74.6% in Austria to 96% in Sweden. (12) In response to a question about the obligation by the government to provide health care for all, only 4% across all countries took the view that the government need not provide for those on low incomes. Only in Belgium (15.7%) was this view held by more than 5% of respondents.

Of course, some commentators have always challenged the idea of a sustainable welfare state, arguing that the European social model was a temporary phenomenon that would eventually collapse in the face of economic reality. Some of the earliest warnings came in the mid 1970s, largely as a result of the economic shock following the 1974 Middle East war, with its accompanying world-wide recession. More recently, pressures imposed by the convergence criteria for joining European Monetary Union have been an important factor. However, perhaps the most important is the challenge posed by the post-industrial society. The traditional model of employment and family life, with male industrial workers in life long employment and supported by non-working wives, is disappearing. (13)
Politicians feared that systems will become unsustainable but they adopted a wide range of cost containment strategies so that, by the 1990s, most European countries had reduced the rate of growth in expenditure on health care as a percentage of national wealth. (14)

Some of the methods involved the introduction of market-based reforms. Thus, some tax-based systems, such as the United Kingdom and Sweden, separated purchasers and providers of health care. (15) Some with social insurance systems, such as Germany, introduced competition between insurance funds. Many increased direct payments by patients, by removing certain drugs from lists of those that can be prescribed or by introducing co-payments for certain services. Some also increased the amount of care provided by the private sector. (16)

While many other factors played a part, including shortages of key workers because of demographic changes and rising public expectations, these policies were linked, by the media and ultimately by health professionals and the public, with a decline in the quality of care in some countries. This was particularly true for countries with tax-funded systems that had tended to spend less on health care than did those with social insurance systems.

By the late 1990s it was apparent that a backlash was occurring in many countries. The United Kingdom abandoned many of its market-based reforms. A British civil servant has noted that “the British public’s sense of justice and fairness was not consistent with the concept of maximising private advantage that underlies the competitive model.” (17) In France, the government constrained the system that had permitted physicians in certain areas to charge higher fees. (18) In Germany the Social Democrat led government reversed many of the pro-competitive elements introduced by its predecessor. (19)

The public perception of these changing policies have been plotted in Sweden, which has experienced substantial changes. (20) During the period of relative affluence in the early 1990s a majority of the population favoured a reduction in public sector expenditure but, by the late 1990s, when the quality of services had deteriorated visibly, this changed, and more people favoured an increase in expenditure.

Taken together, these findings indicate that, while greater efficiency is welcomed, there is little appetite in Europe, across countries with quite different health systems, for radical reforms that are seen as undermining the welfare state.

At the same time many policy-makers are looking at evidence from the former socialist countries in central and eastern Europe that has cautioned against leaving health care (or other elements of social policy) to the ravages of the market. Rapid introduction of market-based systems had calamitous consequences for health, as well as for economic development. The clear message from this period is that while markets may have a place in social policy they must be embedded within a strong institutional framework. (21)

In summary, there is a high degree of popular satisfaction with existing European health care systems. These systems have survived intact in the face of changing economic fortunes and, where fundamental changes have been attempted they have failed or been rejected by a public that places a high value on their underlying concept of social solidarity.
The political embodiment of the European social model

In the mid 1990s, a series of developments placed social protection more centrally on the EU political agenda. One factor was the perception that the EU was increasing seen as a solely economic entity, with the implementation of the single market and competition by countries to attract investment potentially driving down social protection. Another was the recognition that changes in age structure, labour force participation, and gender roles were forcing a rethink of some existing systems of financing the welfare state.

This led to a reassessment of the role of the EU in the field of social protection, (22) which has received widespread support from governments of Member States. Subsequently the Commission has proposed a concerted strategy to modernise social protection, subsequently endorsed by the Council of Ministers,(23) of which one of the four objectives is to ensure high quality and sustainability of health care.(24) This states that “everyone should be in a position to benefit from systems to promote health care, to treat illness, and to provide care and rehabilitation for those who need it.” The Council also stressed the need for full advantage to be taken of advances in information technology, but in a way that supports social inclusion (see later). In the absence of a legal basis in the treaty to act on this issue a new mechanism, “enhanced cooperation”, has been established in which a group of high level officials will examine how to learn from best practice elsewhere. The emphasis on social inclusion as a goal of these actions was further reinforced in the Lisbon European Council in early 2000.(25) In a related action, the EU has since signalled its intention to monitor the impact of the single market on health policy (26)

Conclusion

There is compelling evidence of a shared set of values that have given rise to the welfare state in all EU Member States, which are distinct from those in, for example, the USA. While these values may fluctuate from time to time they appear to be relatively stable. While some politicians have advocated radical reforms from time to time, it is notable that no European country has dismantled its health care system as was done by Pinochet in Chile, with disastrous consequences. (27) Indeed EU Member States have now explicitly stated that equitable effective health care systems are a means of promoting both economic growth and social cohesion in Europe.

The challenge facing the EU is how to take advantage of the Single European market to promote this goal and not to undermine it. As already noted, while Member States have clearly committed themselves to the provision of high quality health care, as Pieters and van den Bogaert have noted elsewhere, (28) they have not so far found a way of including it in a Treaty. As a consequence, legislators and the Court have so far been guided primarily by the imperative to promote free movement. The newly established system of enhanced cooperation does, however, provide a basis from which a future Treaty revision could emerge and is highly likely to promote development of a shared, more concrete vision of how the EU might proceed.

In the remainder of this report we explore how European law on a series of issues relevant to the organisation of health care has evolved so far and how it supports or impairs the ability of Member States to ensure high quality care. First, however, we explore in more detail the policy-making context within which policies related to health and health care are developed. Because of its peculiar relationship with the Treaty, with its organisation and delivery a responsibility for Member States but also identified as an area for co-operation, while also clearly influenced by policies in other sectors, it has developed quite differently from many other areas in which the EU has an interest.
Thus, chapter 2 analyses how health policy has grown from its modest beginnings in the Treaty of Rome, indicating the role of the EU’s decision-making framework in this process. This analysis demonstrates some of the reasons why it has not so far been possible to develop a comprehensive basis for health policy action.

In subsequent chapters, the impact on health care of the freedoms enshrined in the Treaty are examined in detail. These are freedom of movement of people, in this case health professionals and patients; freedom of movement of goods, here pharmaceuticals and medical devices; and freedom of movement of services, here health insurers. Two subsequent chapters examine specific aspects of European law that have relevance for health systems. The first is competition law. A single market can only operate in the presence of open competition across borders, which means that national transactions must not unfairly discriminate on grounds of nationality. This is an extremely complex area because of the many ways in which discrimination may take place, involving the creation of cartels or abuse of a dominant position, as well as the many exemptions, especially where policies involve sovereign actions of governments or social goals. The second is the growth of electronic commerce. This makes cross-border trade much easier, so furthering the goal of a single market, but at the same time it raises issues of regulation where services (such as medical advice) or goods (such as pharmaceuticals) may pose a risk to the consumer. It also has implications for social inclusion, as noted by the EU, as those in greatest need may be least able to access this mode of communication.

The report then concludes by exploring where the EU should go next, to ensure that the single market enhanced health protection in Europe rather than undermining it.

This report cannot hope to be an exhaustive analysis of every aspect of European law that might have an impact on health systems. We do, however, hope that it provides a comprehensive assessment of the main implications of EU law in certain key areas.
CHAPTER 2: THE THEORETICAL BASIS AND HISTORICAL EVOLUTION OF HEALTH POLICY IN THE EUROPEAN UNION

Introduction

Originally embarked upon as an exclusive organisation of six west European states with common economic interests in two industries, the European experiment has come a long way since the visions of Jean Monnet and Robert Schuman were first put on paper in the Schuman Declaration of 1950. Having expanded well beyond the comparatively limited scope of the European Coal and Steel Community (ECSC) established in 1952, the European Union (EU) now wields authority in many areas, social, political and economic. Health policy is one such area, though it is undoubtedly the case that EU competencies in health policy are considerably less developed than those in other areas. This was recognised during the June 1999 European Council Meeting in Luxembourg, when incoming European Commission President, Romano Prodi, announced his intention to establish a new, separate Directorate-General (DG) for health and consumer protection matters (29). The new DGXXIV was established as part of the reform of the European Commission in late 1999. Admitting the need for such a body is one thing: whether it will be able to take account of and effectively deal with all Community health and health care related matters is, of course, another.

It has long been recognised that many other areas of Community policy (such as agriculture, the environment and industry) do impact on health. So although not its primary purpose, this chapter inevitably tackles many of the more important questions that face the European Union in the area of health policy.

Theoretical reflections on EU health care policy-making

The evolution of the European Community into an organisation with supranational qualities has been explored extensively in the academic literature on European integration. The aim of securing peace in post-WWII Europe was actively pursued by the region’s politicians and supported by many of its academics – the latter having sought to articulate the political systems necessary for achieving this goal. Though not offering a detailed analysis of the theories and debates that emerged, this section aims to offer a theoretical perspective on the consolidation of an EU role in health policy.

Beginning with neo-functionalism and intergovernmentalism as the two most influential integration theories, we then turn to meso-level analysis in order to pick up on specific aspects of the policy process. The reason is that although macro theories are germane to ‘history-making decisions’, they “tend to lose their explanatory power” vis-à-vis policy decisions (30). While it may be possible to establish linkages both between and amongst the broader theories and levels of application, this chapter does not seek to make them. Instead, accepting that such an integrated approach does not do justice to the EU as a complex polity unto itself (31) – predominantly because of the generalisations it assumes – we turn our attention to specific instances of where each approach is valid and what it helps to explain about the EU health policy-making process. This reflects a tacit acceptance of the EU as a new system of governance (30, 32, 33), and one which does not readily lend itself to any singular theoretical categorisation. We do not aim to provide a coherent theory of EU health policy developments, and we do not endeavour to examine the relative merits or flaws of the approaches themselves. Rather, we aim to show where and how EU competencies in the health field have developed, by referring to different theoretical approaches where relevant, and why, therefore, there is no singular direction for health policy at Community-level.
The relevance of traditional integration theory

Depending on their point of departure, the early integration scholars of the 1940s tended to follow one of two main lines. The federalists and functionalists were led by the visions of Jean Monnet and the work of David Mittrany (34) respectively. Their focus was on the end-product of political integration in Europe, that is, what form the integrated Europe should take. The transactionalists meanwhile, headed by Karl Deutsch (35), sought to understand the conditions requisite for political integration to be possible in the first place (36). Both approaches served to generate the academic debate that would later culminate in the development of neo-functionalism as the (then) leading theory of European integration.

Neo-functionalism - the ‘spill over’ effect

During the 1950s and 1960s, as a critique of deficiencies in the functionalist conception, neo-functionalism became the theory of choice for academics; particularly amongst American social scientists, with Ernst Haas (37) at the fore. By combining the competition element in the political process of traditional pluralist thinking with the (necessarily) gradual nature of political change understanding proffered by Mittrany, the neo-functionalists sought to show how the European political process was dependent as much on political action as economic determinism.

Central to this understanding was disproving the functionalist idea that a meaningful and lasting distinction could be made between policies involving functional or technical questions, and those which were more political or constitutional in nature. Health policy proves their point. Although the distinction may initially seem applicable – at least in ideal circumstances – health policy is not a uni-dimensional concept or policy field. So though it might be the case that health issues are indeed specific and sensitive enough to merit attention of their own, in practice, health policy proves equally a political as technical (and economic) issue. Member States are, therefore, particularly sensitive where health matters are concerned.

Neo-functionalist theory helps explain how health came to be part of the Community agenda. What is arguably its best-known premise, the concept of ‘spill over’ - where Community authority develops or evolves as a result of policy developments in related fields - is particularly relevant. The idea of integration taking place in small steps where “pressure in one sector could demand integration (or changes in standards) in order to complete the process of policy change” (38), coincides with efforts to establish a health policy role for the Community. While it has been shown that EU health competencies have developed primarily to promote a common market (39), we argue that some aspects (though not all) of the present Community framework seem to have evolved as ‘spill over’ from other provisions relating to this process.

Crucial to the ‘spill over’ premise was that the integration process would prove self-sustaining. In developing this idea as an inheritance from Mittrany, the neo-functionalists attempted to gauge the relevance and role of the new European Community institutions to the integration process. They argued that these new bodies could (and did) foster integration of their own accord as supranational constructs. While the role of the European Court of Justice (ECJ) as guardian and instigator of Community law, which supersedes national legislation, may have been the embodiment of this idea, the Luxembourg Compromise of 1966 shattered it. French President de Gaulle precipitated a constitutional crisis over the use of qualified majority voting vis-à-vis common market decisions, which culminated in agreement on the need for unanimity to pass legislation in instances where “very important [national] interests are at stake”. Health and welfare policy fall within this caveat. Without engaging the specifics of the Luxembourg Compromise, it did serve to underline the point that the integration process was not entirely self-sustaining, and that the Member States remained very much in charge of their own destiny;
especially where sensitive matters of national interest were implicated. Later, however, with the Single European Act of 1986, the integration process was revived, leading to neo-functionalism and its brand of ‘spill over’ specifically.

Several health and health care-related areas within the mandate of the EU can be explained by ‘spill over’. It would appear that these single market aspects of health policy have (necessarily) developed because of Community activities in the broader field of social regulation. The two are, of course, related but Community competencies in the two areas have developed quite separately (40). It is, however, worth noting that social regulation aspects of the single market framework are considerably more developed (41).

For instance, in the area of occupational health and safety regulation, the Community had to establish uniform workplace safety (and environment) standards in order to ensure the working of the single market. The post-1985 Directives on health and safety were passed primarily because the Community wanted to avoid the danger of ‘social and ecological dumping’ (42), where business would be able to take advantage of differences in standards, and hence costs, between Member States. The Community thus sought pre-emptively to avoid a weakening of health and safety measures resulting from increased competition, by regulating occupational health and safety standards upwards. European policy-makers from both the Commission and national governments recognised that extending the Community’s competencies into social areas would in turn benefit its economic functioning. In other words, by trying to establish a ‘level playing field’ for business, it would advance the progress of a single market. This generalisation does not, however, account for differing interests within the wider business community, and in this vein it has been argued elsewhere that larger firms have tended to support higher levels of protection as a means of keeping ahead of smaller competitors less able to meet stricter standards (43).

Another example of this interpretation of ‘spill over’ in the health field, and one in keeping with more contemporary events, is the current degree of attention being paid to food safety. The recent occurrence of food scares in Europe – BSE and nvCJD, dioxin contamination, and the use of sewage slurry in animal feed – has in part undermined consumer confidence in food safety regulation (whether at national or EU-level) (44), and in turn has (had) ramifications for the single market i.e. the world-wide ban on British beef, or the recalling of cola from the Belgian market. Here it is interesting to note that the media have tended to refer to the new Directorate-General established under the Presidency of Romano Prodi as simply the ‘DG for food safety’ rather than acknowledging its more complete role in health and consumer protection. It would appear to be the case, therefore, that food safety has come to dominate the EU health agenda largely as the result of the ‘spill over’ from single market (trade) issues.

**Intergovernmentalism - retaining national control**

Despite the numerous health-related developments created by the ‘spill over’ effect, it is obviously not the sole determinant of the Community’s health competencies. It is clear that the Member States do retain a considerable degree of autonomy where important national interests such as health are concerned. That European integration does not succeed without Member State support – that ‘spill over’ is not an unchecked momentum – is one of the key tenets of intergovernmentalism as the other main theory of European integration.

Developed out of the realist position in traditional international relations theory, with Stanley Hoffmann (45) as its leading proponent, the intergovernmentalist perspective evolved as a critique of neo-functionalism. In seeking to maintain a lid on the potential intergovernmental ‘can of worms’ – for there are varying interpretations relating to institutions (‘institutional intergovernmentalism’), area fields (‘functional intergovernmentalism’), and the ‘three pillars’ of
the Treaties (formal ‘intergovernmentalism’) (46) – we remain within a simple understanding
which asserts the pre-eminence of the Member States over the Community institutions in the
integration process. That said, it should be borne in mind from the outset that one of the major
flaws in this conception is that the intergovernmental focus on individual actors (Member States)
pursuing self-interested goals may serve to elucidate their behaviour in the integration process,
but does not necessarily explain policy outcomes.

Health policy in the Community thus raises several important points. First, the issue of national
self-interest may (implicitly) help to explain, in general terms, why health policy has not been
devolved to Community authority by the Member States. For the Community to exercise a wider
role in health policy would require a new Treaty provision. It would necessarily be one that
recognised public health as a multidimensional concept – both in theory and practice – rather
than limiting it only to tackling specific diseases and “taking health into account in other
Community policies”. Member States are not prepared to give the Community such a role
primarily because they themselves have not been able to address some of these key issues
themselves. Notwithstanding their acceptance of concepts such as solidarity and universal health
care coverage, it is noteworthy that, historically, European governments have, for political and
practical reasons, been unable – if not unwilling – to institute the changes a wider health policy
framework would require.

For many European governments since WWII, especially those that were liberal or right-wing, the
more centralised state role this type of framework would necessitate proved ideologically
untenable. Accordingly, they did not attempt to make the connection between the wider
determinants of health and a comprehensive health policy framework. As has been summarised
elsewhere, “pursuing a social agenda in a world dominated by neo-liberal assumptions about the
primacy of needs of the economy has not proven easy for health advocates.” (47) In the UK for
instance, although a national health system (NHS) was already in place, the pro-market,
conservative government of Margaret Thatcher did not seek to address the question of social
inequalities in health. Even where ideology was not so much the mitigating factor, and social
democratic parties were in power such as in Germany, Austria and the Netherlands, the social
insurance-based healthcare systems they employed were (and remain) unable to accommodate
the changes a wider approach would involve.

A second way in which intergovernmentalist theory provides a useful backdrop to health policy in
the Community, is via Hoffman’s division between matters of so-called ‘high’ versus ‘low’ politics45.
The former encompasses security, defence and foreign policy, while the latter is concerned with
welfare and economic policy. This differentiation was designed to show the limits of the neo-
functionalist argument that integration was a self-sustaining dynamic. It could not be taken as a
foregone conclusion that the Member States would accept integration in areas of ‘high’ politics
simply because they were more or less agreed on ‘low’ politics concerns such as single market
tariff elimination, and the requisite social regulatory policy implications. In terms of positioning
health policy within this division, neither category seems ideal; though perhaps by association
with welfare policy, health policy would qualify as a ‘low’ policy area. In accepting this, it still
should be pointed out that while health policy may indeed be linked to questions of welfare, the
two do not always amount to the same thing. Nevertheless, assuming that health policy is indeed
a ‘low’ politics matter for the Community – where intergovernmental co-operation could be
expected – why then has there been national resistance to its so-called europeanisation? The
reason is that, for national governments, aspects of health and healthcare are in fact ‘high’ policy
areas. Thus, as Member States decide the pace and direction of integration – and not the
European institutions through some sort of momentum of their own – it ought not be surprising
that health policy remains predominantly a national-level concern. The exception is those aspects
of health and health care policy that fall within the single market context and developed primarily through ‘spill over’.

Community health and healthcare competences, therefore, exist where economic priorities are concerned (‘low’ politics) but does not involve the exercise of executive powers with respect to developing a comprehensive health policy framework at EU-level (‘high politics’). As such, a competence division exists where health and some healthcare matters are currently a shared responsibility between the Community and Member States.

Finally, a third level on which intergovernmentalism is relevant to health policy in the Community is with respect to the more recent liberal intergovernmental approach. According to Moravcsik (48), this perspective takes the emphasis on the Member States one step further and questions the whole validity of supranational decision-making itself. The focus here is on interdependencies between national decision-making and international co-operation. The argument is that although national governments are the main actors and retain control over the integration process, they are motivated (if not in some cases forced) to pursue further integration because of a combination of externalities and particular internal circumstances. In this vein, one can look to the pressures exerted by the global trade liberalisation regimes of the General Agreement on Trade and Tariffs (GATT), and now the World Trade Organization (WTO) as giving rise to further integration in Europe. Or else, on a more policy-specific level, it may be in part because of potential negative externalities such as air and water pollution, that Member States have agreed EU environmental standards.

According to theories of liberal intergovernmentalism, Member States in response to these pressures are willing to pool endeavour and effort towards further integration as manner of consolidating their position relative to others. In relation to health policy, Member States are thus open to persuasion that certain aspects of policy, such as occupational health and safety and those matters relating to the single market (i.e. free movement of goods and professionals), are better regulated on their behalf by the EU. Others, which are more sensitive such as healthcare financing and the pricing of medicines, are guarded jealously. Leaving aside the deficiencies in this wider assessment – for the European institutions have indeed had a major part to play in the integration process – the liberal intergovernmentalist approach (and intergovernmentalism in general) does offer some insight into what motivates the integration process in Europe; and in turn, why certain aspects of health policy have been mandated the Community and others not. Despite this, it should be noted that neither neo-functionalism nor intergovernmentalism has been shown to generate testable hypotheses regarding the conditions under which supranational institutions exert an independent causal influence on either EU governance or the process of European integration (49).

**Perspectives on process**

The duality or competence-sharing between the Community and Member States where health policy is concerned is perhaps captured in the understanding of European law as *supranational* and European policy-making as *intergovernmental* (50). More specifically, health-related policy-making is co-operative, as many of the issues remain decided at national level. European legislation meanwhile finds its constitutional basis in the Treaties and, via the European Court of Justice (ECJ), much of it supersedes that of the Member States. Infringements against Treaty stipulations can result in sanction for the offender, though the development of EU policies/competencies within the framework set down by the Treaties first requires each Member State to agree in the Council of Ministers. Health policy finds itself in the grey area of the middle.
Related to the broader theories of integration and the intergovernmental-supranational dichotomy which, after all, was at the heart of the differences between neo-functionalist and intergovernmental thinking, is the question of process. The original EEC Treaty of Rome (1957) introduced two political dynamics known as ‘positive’ and ‘negative’ integration towards a European common market. These two processes are relevant to our discussion on Community health policy as they support the earlier arguments regarding ‘spill over’ and intergovernmental bargaining over sensitive policy areas. Positive integration involves the establishment of common policies to define the conditions under which European markets operate, whilst negative integration is concerned with the elimination of (national) barriers to the free movement of goods and services within the Community (51). The former involves the active harmonisation of national regulations such as in the fields of consumer protection and environmental risks, and goes through the Council of Ministers (intergovernmental). The latter involves the rescinding of national authority – liberalisation – to the Community through tariff and quota reductions, and is therefore a more straightforward process given the Treaty obligations (supranational).

The two processes were envisaged to run concomitantly towards the implementation of the common market by 1969, but the Luxembourg Compromise of 1966 represented a major setback. The requirement that unanimity be achieved in the Council of Ministers resulted in an awkward decision-making process over single market issues – though the Luxembourg Compromise itself is rarely invoked – and meant that negative integration came to the fore. This hindrance to positive integration accorded the European Court a prominent role in the integration process as arbiter over matters involving the single market. Indeed, through a considerable amount of case law generated between 1970 and 1985, the court has been credited with giving rise to the Single European Act (SEA) of 1986 via a process of negative integration (52). In other areas, however, the court was successful in generating positive integration. For instance, in the broader field of social policy – as separate from those areas of social regulation related to the single market – a host of legal decisions has granted the Community a greater role than was perhaps envisaged in 1957. A Charter outlining a Community framework for the development and implementation of proposals in social fields has existed since 1989. This is in part because social matters (health and welfare included) have been regarded as ‘low’ politics matters within the Community context. Nonetheless, the Court’s role in health has been a combination of positive and negative integration.

Expansive rulings in some cases of social policy have ensured the Court a leading role in issues of gender equity and social protection, and has resulted in national changes that would otherwise have taken considerably longer to occur (53). Where health matters are concerned, consumer protection issues, food safety and environmental interests fall within this pro-active ECJ mandate; and in many Member States (particularly those of southern Europe) it has resulted in completely new legislation in the absence of earlier national regimes (54). In areas such as these, therefore, the EU legal system has had a positive (integration) effect on health policy in the Community.

In this vein, it is also relevant to consider the distinction between product regulation and process regulation. Product regulation involves the establishment of common standards on goods and services; where intergovernmental agreement can be expected because differing national product safety and quality requirements would undermine the market harmonisation goals of Articles 30 and 34. Thus, despite derogations under Article 30 on the grounds of public health, public policy

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\textsuperscript{a} Articles 30 and 34 (now Articles 28 and 29 of the Amsterdam Treaty) read: “Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between member States.” and “Quantitative restrictions on exports and all measures having equivalent effect shall be prohibited between member States.”
or national security, amongst others, it is assumed that Member States will reach agreement on product regulation because of their common interest in the single market. This is not the case for process regulations such as environmental and occupational safety requirements. Here, the absence of a ‘Euro-regime’ could in theory mean Member States cutting back on national standards to increase competitiveness (51). The incentive for Member States to seek harmonisation in these areas is of course to avoid having to compete on an unequal footing with those countries with more lax standards. But, it was only with the Single European Act that EU-level regulations became possible, if not necessary. And even then – as was mentioned earlier – it was up to the Commission to ensure that a situation of social and ecological dumping did not take place. Positive integration can thus be linked predominantly with progress in the harmonisation of product regulation, though it has had a much weaker impact on harmonising process regulation.

The European Court of Justice: the 'motor' of integration

Beyond the social matters mentioned earlier, the European Court of Justice has played a major part in raising health policy issues. This stems from its role in ‘constitutionalising’ the Treaties into something of a European charter, in turn promoting a juridification of the decision-making process (55). Along with the Commission, the Parliament and the Council, the Court was one of the original four institutions as established under the Treaty of Rome; Articles 164-168A refer to the ECJ and its powers: “...to ensure in its interpretation of the Treaty that the law is observed”. Its three main purposes can be summarised as: to judge in disputes brought by the Commission or the Member States against the Member States - concerning questions about the legality of action and non-compliance; judicial review of institutions regarding damages, the annulment of actions, and the requirement of action; and to act as preliminary reference procedure i.e. system whereby national courts can refer questions on EC law to the ECJ, which will decide and then pass it back down (this constitutes the majority of its work). In practice, its role often involves filling in the gaps that have developed with respect to the application of the Single European Market.

Before the seminal Van Gend en Loos case in 1963 (56), the Court had a limited role. In this case a private firm sought to invoke EC law against the Dutch customs authority - something that had hitherto not been attempted - and the ECJ decided that individuals did in fact have the right to invoke EC law. It proved a controversial decision in that the ruling was based on the argument that EC law was sui generis, as it marked the creation of an entire new legal order which allowed for individual invocation. More importantly, it resulted in the principle of ‘direct effect’ applying to all primary Treaty articles. This means that Member States must directly enforce EU law that is clear and precise enough to require no implementing legislation on the part of the Member States; that it is relevant and can be invoked by private citizens.

Direct effect had originally only been applied to narrow Treaty provisions, but since the 1970s the idea of horizontal direct effect meant that individuals could take each other to the higher court. Thus, there are two types of direct effect: horizontal, which is applicable to individuals such that they can defend their rights against other individuals or legal entities i.e. companies; and vertical, which enables citizens to defend their rights against the state. However, while Regulations have both effects, the Court ruled in the 1986 Marshall case 1986 that Directives (as the most commonly used instrument) could only be invoked against a state as they must be transposed
into national law, and were thus only vertical. It should, of course, be noted that this decision was taken in the face of much dissent.

To compensate for the lack of horizontal direct effect over Directives, however, the ECJ developed doctrine of 'state liability' where the state can be held liable for all national infringements of EU Directives. This was based on the 1991 Francovich case (57) when the Italian government was held liable to pay redundancy compensation to employees when a firm went bankrupt. This was because the Italian government had failed to transpose a Directive on such 'guarantee funds'. The decision caused problems as the Italian courts queried the possibility of suing the state for its failure to provide the required institutions. They concluded that it was indeed possible, but only providing that the losses were incurred due to state failings. The doctrine of state liability/responsibility that resulted led to an increase in Member States compliance with Directives, and indeed, direct effect has resulted in a massive increase in the number of cases brought before national courts in the name of European law. Direct effect thus means that European law is more like national than international law, where individuals cannot invoke international law unless it has been transposed into domestic law.

The other major principle established by the Court regarding the sui generis status of European law was the 'doctrine of supremacy'. In the 1964 Costa case (58), the Court ruled that, in the event of conflict, national law was to cede to European law. This was not accepted quite so easily as direct effect, and the Italian, German and French courts in particular engaged in lengthy negotiations with the ECJ. Human rights protection was a main issue, and the German and Italian constitutional courts retained the right to review Community law against their own human rights standards. The Court, however, went on to include human rights protection as a fundamental principle of European law, and has since built up a considerable volume of case-law. Supremacy would appear a logical corollary of direct effect, and has of course ensured that the ECJ plays a major role in the integration process; in particular through single market harmonisation of individual sectors.

Direct effect promotes legal integration amongst the Member States, and as a corollary, political and economic integration vis-à-vis specific rulings. Thus, cases such as Dassonville (59), which rendered all impediments to intra-Community trade illegal; and Cassis de Dijon (60) which led to the principle of 'Mutual Recognition' - which itself led to the Single European Market - fostered economic integration. Direct effect also led to an active role for the Court in establishing Community-wide gender equality i.e. the Defrenne cases in 1971 and 1976, and Article 119 on 'equal pay' was in essence re-interpreted by the Court. The supremacy of EU law also represents a 'Europeanisation' of national laws and provisions. Together, they represent the underlying legal-constitutionalist doctrines of a federal legal system.

Consequently, it is not surprising that many analysts have argued that the strong legal dimension has had a major influence on the policy process: policy-makers must take account of the legal meanings of the texts they draw up; policy advocates look for legal rules to achieve their objectives; policy reformers can sometimes employ case law to alter the impact of EU policies; and choosing the right Treaty provision to apply can be key, as the 2000 Tobacco Directive showed (61). That said, one ought equally to recognise that the ECJ’s integrationist activism has not been linear (62), and that it has often responded to the pace of integration rather than generating it. Nevertheless, we see that the Court has indeed had a considerable, if predominantly indirect, hand in the field of health policy.

There are, for instance, numerous rulings covering health care, medicines, the environment, and workplace health and safety amongst others (63). Indeed, the Court has delivered numerous ruling vis-à-vis pharmaceuticals (see chapter 5) and their distribution in the Community; especially
as pertains to the practice of parallel trade (64). On the other hand, pharmaceutical companies have themselves been successful in many of their lobbying endeavours at both national and EU-level on specific issues; such as being granted extended patent protection on their products (65), that also contributes to the shape of the Community's health policy mandate. Without looking any further at the Court and its unique position, it is sufficient to note that it has developed as a major contributor to EU health policy.

We now describe a synoptic history of establishing Community health and health care competencies.

**Establishing Community Health and Health Care Competencies: a synoptic history**

**The early Treaties**

The rationale behind the foundation of the European Coal and Steel Community (ECSC) indicates that European integration has for the most part been economically-driven even though political motivation, was the underlying factor (66). Despite being an outwardly economic enterprise, the ECSC was equally a political undertaking. It was set up as much to present a unified industrial front in the coal and steel industries as it was to help stabilise post-WWII western Europe (67). This was in keeping with the federalist and institutional vision of a ‘United States of Europe’ proposed after WWI as a manner of ending the historical cycle of wars in Europe (68). Originally signed by seven of the current fifteen EU Member States, the 1952 Treaty of Paris establishing the ECSC set the stage for future and further European integration.

The ECSC was an ambitious plan, not only because it established a large free trade area but also because it laid the foundations for what later became the European ‘common market’. This required the setting up of regulatory, overseeing, and standards bodies, which gave the new European organisation its first characteristics of supranationalism. These characteristics have continued to be strengthened and ‘fine-tuned’ through subsequent Treaties. Social concerns, far less specifically health-related ones, were not an integral part of the Paris Treaty’s provisions; although in Article 55 it did make allowances for research and co-operation between Member States with respect to the health and safety of workers in the coal and steel industries. The Commission was expected to “promote technical and economic research relating to the production and increased use of coal and steel and to occupational safety in the coal and steel industries”. Achieving this involved raising levies on Community coal and steel products, and the use of part of these levies to finance coal and steel research programmes.

In 1957 the Treaty of Rome was signed against the uncertain backdrop of a burgeoning Cold War and the still fresh memories of the Korean War. It sought to build upon the economic successes of the ECSC, as well as readying Europe to face the potential ‘Communist threat’ posed by the geographically proximate and influential Soviet Union. It established two separate contracts, the European Atomic Energy Community (Euratom) and the European Economic Community (EEC). The former includes a chapter on health and safety at work, and led to the early establishment of standards and safety levels for protection against ionising radiation; not only of workers, but also the general population. The latter – which came simply to be known as the European Community - was, however, arguably the more important of the two. More than just consolidating the free trade area initially instituted by the ECSC, it sought to “promote throughout the Community a harmonious development of economic activities, a continuous and balanced expansion, an increase in stability, an accelerated raising of the standard of living and closer relations between the states belonging to it.”
This objective obviously implied an expansion (or at least change) in focus, by indicating that the Community would necessarily be better served in its economic undertakings (single market) through an additional commitment to social affairs. It was nevertheless already clear that the free movement of goods and services under a free trade agreement would involve medicines, biotechnology products, health insurance, and have implications for healthcare; yet these issues were not dealt with specifically (69). Health policy (including public health) did not appear as a separate issue within this proposed social agenda, and was instead incorporated within the more general field of health and safety at work.

Between the 1960s and early 1980s there was a relative lapse in interest in the integration process in Europe; a period generally referred to as ‘eurosclerosis’. Nevertheless, during this period several Scientific Committees were established to look at specific Community-relevant issues (some of which were health-related). It was not until 1986 with the Single European Act (SEA), however, that the integration process was substantially re-awakened.

The SEA established 1992 as the date for the institution of a true Single European Market for the free movement of capital, goods, and labour between signatories. To achieve this, the SEA not only recognised, but also emphasised, that greater and closer co-operation in social, economic and environmental affairs between Members would be needed; such that renewed impetus could be injected into the integration process. Nevertheless, as the extension of the Community's interests into social fields (and health specifically) was only undertaken within the context of completing this single market by the 1992 deadline, the SEA was regarded by some as not going far enough (70,71), particularly given the earlier, more social implications of the Treaty of Rome.

Thus, despite acknowledgement that the SEA would have an effect on health and healthcare outcomes in the Community (72), only those health-related matters that would foster development of the single market were dealt with. Although concrete social matters were given more prominence under the text of the SEA, health policy (including public health) was again not treated as a distinct policy area. Rather, it was once more subsumed within the broader framework of health and safety at work. Nevertheless, the SEA did result in an extension of the Community’s scope for action in the field of occupational health and safety, and environmental and consumer protection (relating particularly to foodstuffs, pharmaceuticals and so-called ‘dangerous substances’), as well as establishing the legal basis for the single market to take consumer health protection requirements into consideration.

**The Single European Market**

Recalling the more theoretical issues raised in the previous section, we now consider what the direct results of the Single European Market on the EU's health competence has been. One of the most obvious outcomes of the 1986 SEA, as listed in Figure 2.1, is that early Community initiatives covering health matters reflect more of an economic and single market priority than they espouse health concerns. It “… required the Commission to take, as a base, a high level of protection in its proposals concerning health, safety and environment and consumer protection, as they relate to the working of the single European market.” (73) One of its long-standing aims in the health field for instance, has been the establishment of a system for the mutual recognition of professional qualifications in the Community (including doctors, dentists, nursing and paramedical staff) (39). With the intention of allowing doctors who have qualified in one Member State to practice in another Member State of their choosing, the Community has adopted a series of Directives (two in 1975 (74,75), a third in 1986 (76), and a fourth – incorporating the previous three – in 1995 (77)).
Another example of health decisions being taken within a single market context pertains to medicines in Europe. Despite the creation of a unique body, the European Medicines Evaluation Agency (EMEA) – unique in that it is not simply concerned with the dissemination of information, but is in fact quasi-regulatory – the Community has failed to address key issues concerning the pricing and reimbursement of pharmaceuticals. The focus has instead been on regulating market authorisation requirements, advertising and package-labelling rules, and the information content of inserts for pharmaceutical preparations. While this is partly due to the subsidiarity principle – under which matters pertaining to national health systems are beyond Community competencies – other important issues associated with a medicines industry have not been addressed.

The creation of the single market has, therefore, had a dual role in the development of an EU health policy framework. On the one hand, as it enables the Community to regulate only in those areas outlined above, it has not had a fundamental impact on national health policy regimes. Consequently, it has been argued that national health policy frameworks and healthcare systems will continue to prevail in the EU. On the other hand, the SEM has served as an important magnet securing intergovernmental agreement on the economic aspects associated with health policy in Europe; although it must be stressed that these do not amount to a coherent strategy.

This trade-off notwithstanding, the single market has nevertheless shown that health policy matters are not the sole purview of national policy-makers. They are now divided between the Community and the Member States, even if the balance is not an equitable one.

The ‘modern’ Treaties

The Treaty on European Union (Maastricht)

After the SEA came a series of intergovernmental conferences (IGCs) to work out the specifics of achieving the single market on time. These in turn led to the Treaty of European Union (TEU) in 1992. In amending the Treaty of Rome, the TEU (Maastricht Treaty) represented the formalisation of the Community’s first real powers with respect to health policy; although it should be pointed out that an earlier impetus for the development of a Community role in cancer came from a 1985 Council of Europe decision inviting the Commission to propose such a programme. Equally, it is important to note that, prior to the Maastricht negotiations, the Community Charter of the Fundamental Rights of Workers (referred to simply as the Social Charter) was signed in 1989 and had implicit relevance to health matters. Although the charter may only have been a general articulation of a wider philosophy for the Community rather than addressing specific matters such as health – and was perhaps undermined by the UK’s refusal to sign – it did serve to highlight particular areas that were then implemented under the Maastricht Treaty.

Specifically, the new Treaty gave the Community concrete legal competencies related to health policy via 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, and with regard to achieving this objective, Article 129 (since referred to as the ‘public health Article’) delineated a rudimentary framework whereby the Community would meet this obligation. It would do so by “encouraging cooperation between the Member States and, if necessary, lending support to their action.” Community action would involve only “the prevention of diseases, in particular the major health scourges, including drug dependence”. The promotion of “research into their causes and their transmission, as well as health information and education” were specified as the primary means by which the Community was to achieve its objectives. In terms of rhetoric, perhaps the

Subsidiarity involves the treatment of policy areas at the lowest level at which they can effectively be undertaken, and is more closely examined in relation to health in Section 3.3.
key phrase in this new provision, at least as regarded the potential wider implications of the Article, was that “health protection requirements shall form a constituent part of the Community’s other policies”. This seemed to indicate that issues related to health policy and public health would necessarily be taken into consideration in the future development of all other Community policies; something that both the Community institutions and the Member States would have to respect.

Yet, despite this apparently clear statement of intent, it has proven vague both in interpretation and practice. When combined with the other provisions of the Article, particularly the specification of disease prevention and health protection as the Community’s two most important priority areas – the new Article failed to provide a comprehensive definition of public health that could be used in Community policy-making. It is also interesting to note that in other areas specified in the Maastricht Treaty, the commitment to such a horizontal approach has been decidedly stronger; most notably in environmental protection, where Article 130r includes the provision that “Environmental protection requirements must be integrated into the definition and implementation of other Community policies”.

Articles 129 and 3(o) were not the only new provisions to appear under the Maastricht Treaty, and neither are they the only ones impacting on health in the Community (Box 2.1). The TEU also introduced Article 3(b) which is otherwise known as the principle of subsidiarity. Establishing the principle that the EU may act “only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community”, subsidiarity empowers the Community to act only in instances where it can be more successful than an individual Member State in achieving a particular objective. In the field of health, subsidiarity applied particularly to healthcare financing and provision, which were to remain the purview of Member States\(^\text{d}\). While originally developed by then Commission President Jacques Delors as a means of developing a more transparent legislative process, subsidiarity in effect became a “political panacea for the Community’s manifest ills” (81). The subjectivity of interpretation meant that both the Community and Member States could invoke subsidiarity in order to either keep out, or else include, the other in various policy areas.

\(^\text{d}\) Rather than simply falling under the subsidiarity principle, the fact that healthcare services were beyond the Community remit, was formalised in the new public health article (152) under the Treaty of Amsterdam.
Box 2.1: Maastricht Treaty articles with a health influence

<table>
<thead>
<tr>
<th>Article(s)</th>
<th>Provision</th>
</tr>
</thead>
<tbody>
<tr>
<td>3(o)</td>
<td>Stipulates that the Community will contribute to the attainment of a high level of health protection for its citizens</td>
</tr>
<tr>
<td>3(s)</td>
<td>Defines that one of the objectives of the Community should be to contribute to the strengthening of consumer protection</td>
</tr>
<tr>
<td>30</td>
<td>Prohibits quantitative import restrictions between member States</td>
</tr>
<tr>
<td>34</td>
<td>Prohibits quantitative export restrictions between Member States</td>
</tr>
<tr>
<td>36</td>
<td>Permits restrictions on imports and all measures having equivalent effect on grounds of the protection of health and life of humans, animals or plants</td>
</tr>
<tr>
<td>43</td>
<td>Agriculture</td>
</tr>
<tr>
<td>48-51</td>
<td>Free movement of workers</td>
</tr>
<tr>
<td>52-58</td>
<td>Rights of establishment</td>
</tr>
<tr>
<td>59-66</td>
<td>Free movement of services including insurance</td>
</tr>
<tr>
<td>75(1)</td>
<td>The need to introduce measures to improve transport safety</td>
</tr>
<tr>
<td>100-102</td>
<td>The approximation of laws related to the single market</td>
</tr>
<tr>
<td>118</td>
<td>Prevention of occupational accidents and diseases and occupational hygiene</td>
</tr>
<tr>
<td>129</td>
<td>Health policy and Public health</td>
</tr>
<tr>
<td>129a</td>
<td>Consumer protection</td>
</tr>
<tr>
<td>130f-130q</td>
<td>Research</td>
</tr>
<tr>
<td>130r (130r-130t of Title XVI)</td>
<td>Environment and protection of human health (Environment)</td>
</tr>
<tr>
<td>117-125</td>
<td>Related to social provisions and the setting of a Social Fund</td>
</tr>
<tr>
<td>130a-130e</td>
<td>Economic and social cohesion; the Protocol on social policy; and the Agreement on social policy concluded between the Member States with the exemption of the United Kingdom</td>
</tr>
<tr>
<td>130u</td>
<td>Fostering economic and social development of the developing countries</td>
</tr>
</tbody>
</table>

The subsidiarity principle has been criticised as vague and ineffective. Whilst it has, on the one hand, been interpreted as representing a guiding principle for Community policy, on the other, it appears as a legal restraint on Community activities. As a policy that was decidedly more political than legal in its implementation, subsidiarity has served to further hinder the Community’s already limited role in matters relating to health by ensuring that certain matters, specifically those related to health services, remain the responsibility of Member States. Here it is interesting to note an informal remark made by Jacques Delors to then British Prime Minister John Major at the 1995 European Summit meeting in Essen; that, in his view, health was in fact an ‘inappropriate area’ for EU involvement (B2). This seems a somewhat ironic comment following years of Commission activity to guarantee the Community a more influential role in EU health matters. Nevertheless, from the framework established by the Maastricht Treaty, several Community-level initiatives and action programmes in the field of public health were developed and these are examined later in this paper.
Box 2.2: Article 129 of the Maastricht Treaty on European Union

The Community shall contribute towards ensuring a high level of human health protection by encouraging cooperation between the Member States and, if necessary, lending support to their action.

Community action shall be directed towards the prevention of diseases, in particular the major health scourges, including drug dependence, by promoting research into their causes and their transmission, as well as health information and education.

Health protection requirements shall form a constituent part of the Community’s other policies.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the area referred to in paragraph 1. The Commission may, in close contact with other Member States, take any useful initiative to promote such coordination.

The Community and the Members shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

In order to contribute to the achievement of the objectives referred to in this Article, the Council:

- acting in accordance with the procedure referred to in Article 189b, after consulting the Economic and Social Committee and the Committee of the Regions, shall adopt incentive measures, excluding any harmonization of the laws and regulations of the Member States; and
- acting by a qualified majority on a proposal from the Commission, shall adopt recommendations.

Looking at the particulars of Article 129 (Box 2.2), while it may initially have appeared to represent exactly that which the Community was lacking, namely, specific competencies in the field of health policy (including public health) - this proved not to be the case. First, in citing “the prevention of disease” as the Community's main objective, it did not provide a real definition of public health around which wide-ranging competencies could be established. Rather, it led to a framework based almost entirely on specific diseases, despite some Commission officials having expressed their desire for a wider interpretation (83). Second, a successful (health) policy initiative requires a clear view and statement of aims, priorities, limitations, responsibilities, methods and resource implications; and the new Article contained very little of these (84). Also, it was unclear what exactly was meant by a 'high level of human health protection'; let alone how this could be measured.

Later, in a 1995 Report published by Directorate-General V of the European Commission (Employment, Industrial Relations and Social Affairs), the Community defined ‘protection’ as enabling the Commission to assess proposed policies to ensure that they “do not have an adverse impact on health, or create conditions which undermine the promotion of health.” (85) Although responsibility for attaining this objective was laid upon the Community as a whole, if the Community could only be involved through the encouragement of ‘co-operation between Member States’ and ‘lending support’ where necessary, the question arose as to who was in fact responsible for carrying out the necessary measures? Furthermore, in establishing that Community intervention was only possible with respect to encouraging national co-operation in
the field of disease prevention (specifically the ‘major health scourges’), and in encouraging collaboration with third countries and international organisations, it was clear that the Commission’s role was supplementary rather than pro-active (86).

Equally vague were the measures necessary to undertake these goals. With little more than catch-phrases to the effect of ‘coordinate’, ‘foster’, and ‘contribute’, very little was stipulated as to how the provisions could be implemented; especially with harmonisation measures having been ruled out. The term ‘incentive measures’ was also undefined within the provisions. Although a definition was later specified as “Community measures designed to encourage cooperation between Member States or to support or supplement their action in the areas concerned, including where appropriate through financial support for Community programmes or national or cooperative measures designed to achieve the objective of these articles” (87), Article 129 did not make this clear at the time.

The Article was just as opaque regarding its identified priority areas for Community action. It did not explain the term ‘major health scourges’; and even the one that it did name, drug dependency, did not constitute a specific health matter (88). Finally, as recommendations are not a binding legal instrument within the Community, the Commission’s ability to ‘adopt recommendations’ did not necessarily constitute a significant role in health policy. That said, while recommendations are legally less potent than regulations and directives, they are potentially very influential. One could, for instance, imagine the repercussions if an incident similar to the blood transfusion scandal in France during the 1980s were to arise today, and a Member State had chosen to ignore the recent Council recommendation on blood and plasma donor suitability (89). Hence, the Commission’s ability to adopt only recommendations is not de facto representative of a marginal role; though a stronger remit might indeed have had more effect. Thus, although it seemed that the “ideological objective” laid out by the Article “meshed neatly with the fact that the Community had wanted to take and had indeed taken various initiatives in the health field but sometimes with or without any very adequate or specific Treaty base” (90), the Article proved little more than a general statement of intent couched in vague provisions. What it did do, however, was to set the tone for the future direction of the EU’s role in health policy. By laying down a commitment to “the prevention of diseases, in particular the major health scourges”, it entrenched the disease-based approach which characterises the present Community approach.

**The Treaty of Amsterdam**

The Treaty of Amsterdam was developed at the 1997 IGC in Amsterdam; though it only came into force on 01 May 1999 following a long ratification process. Although the original agenda for the conference did not feature health, the Treaty of Amsterdam includes a new role for the Community in the field of health policy. It effected a revision of the TEU Article 129 through the addition of several new provisions and changes to parts of the existing text, and renamed it Article 152 in the consolidated text (Box 3, overleaf). Because of the earlier-cited criticisms of Article 129 and the failings they reflected, much was expected of the plans to revise the Community’s health policy framework. Expectations for a comprehensive re-evaluation and overhaul of the Article’s provisions were not, however, realised in the new Article. Although it does represent a revision of Article 129, in looking beyond the superficial, it seems that Article 152 has not only failed to address several key deficiencies of its predecessor, but may even run counter to other stated Community objectives.

*The Treaty of Nice, which has yet to be ratified, does not change the provisions that relate to health policy.*
Box 3: Article 152 of the Treaty of Amsterdam

1. A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities. Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating scourges of danger to human health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education.

The Community shall complement the Member States’ action in reducing drugs-related health damage, including information and prevention.

2. The Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.

3. The Community and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

4. The Council, acting in accordance with the procedure referred to in Article 189b, after consulting the Social and Economic Committee and the Committee of the Regions shall contribute to the achievement of the objectives referred to in this Article through adopting:
   (a) Measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member States from maintaining or introducing more stringent protective measures;
   (b) By way of derogation from Article 43, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;
   (c) Incentive measures designed to protect and improve human health, excluding any harmonisation of the laws and regulations of the Member States.

The Council, acting by a qualified majority on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article.

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. In particular, measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

First, terms such as the ‘co-ordination of activities’, and ‘major health scourges’ again appear without adequate explanation. What specifically constitute ‘incentive measures’ as regards public health is also not defined. Second, although the new provisions appear to resolve the ambiguities raised under Article 129’s loose commitment to “the prevention of disease” – by restating the Community’s objective as “improving public health” – closer examination again reveals the lack of an adequate definition of public health incorporating the wider determinants of health. Despite a firm pledge to “ensure a high level of human health protection in the definition and implementation of all Community policies and activities”, the provisions fail to specify how this will be done; beyond again referring to the Community’s complimentary role in undertaking action
with Member States. This can be seen as constricting present Community activities and impeding the initiation of new and innovative proposals by the Commission (91).

The new provisions also make it clear that Community action must respect the responsibilities of Member States. According to the chair of the European Parliament Committee for the Environment, Public Health and Consumer Protection, the reason for this is that “the delivery of health care to individual people is better organised nationally and locally than it could ever be from Brussels... [and] the British Department of Health and its equivalents in other Member States would never tolerate interference in the way they run their affairs” (92). Yet, because of the impact many Community activities have on the provision of health services (both directly and indirectly), this stipulation appears to gainsay other goals. For instance, the Commission’s 1997 Communication on ‘Modernising and Improving Social Protection’ calls for a ‘European dimension’ to health services, specifically regarding the “need to improve efficiency, cost-effectiveness and quality of health systems so that they can meet the growing demands arising from the ageing of the population and other factors” (93). It is difficult to see how this aim for a ‘European dimension’ to health services can be pursued effectively when health services are not covered under the Treaty. It must, however, be pointed out that the Commission’s views are not necessarily representative of those held by the Community, as Member States may not accept an EU role in health services. Nevertheless, excluding health services in this manner may also fuel citizens’ perceptions that the EU is not dealing with the practical realities of health, and that the Community is not undertaking those activities which would appear most necessary.

With respect to health policy, it is interesting to note the former Social Affairs Commissioner Flynn’s statement on a future EU health policy, that “while it is clear that the provision and financing of health care is a matter for Member States, a Community policy on public health which ignored the development and the effectiveness of health systems would be wholly inadequate” (94). This would support an earlier point made by a British Member of the European Parliament (MEP) who, in 1995, called for the harmonisation of national laws and regulations to ensure minimum Community standards in healthcare (95). It is interesting to note that some purchasers and providers of healthcare are already operating outside of their respective national frontiers, for example some private health insurance companies (96). It is also important to recognise the increase in so-called ‘medical tourism’ where citizens of one country travel to and use the healthcare facilities of another (90). Without addressing the practical implications the harmonisation objective might imply, it would, therefore, appear that the Commission’s position on healthcare remains unclear.

Another issue to emerge from Article 152 is the addition of a statement on the health effects of addictive drugs. Traditionally, drug dependency and its health effects are assumed under the remit of national ministers for social affairs and crime, rather than those with responsibilities for health. Illegal drugs, their trafficking and trade (and crime associated with them) have, therefore, generally been deemed matters of ‘internal affairs’ beyond the scope of EU law. Despite the perhaps curious nature of this inclusion, the involvement of the Community in matters pertaining to drugs does represent a positive development as it recognises the health aspects associated with the use of illicit drugs.

Equally noteworthy is the specification of provisions regarding the safety of blood, organs, substances and blood derivatives of human origins, especially given the detail in which they are explained in the text. The addition of these issues to the ‘health’ Article may initially serve to indicate that national arguments over the safety of such products should not hinder their free movement within the single market, but later statements would seem to weaken this. Specifically, subsequent affirmations to the effect that Member States will not be prevented from instituting
their own national measures (provided they are more stringent than the Commission’s) reflects this lack of clarity.

On the basis of these criticisms the new Article 152 has been deemed a ‘missed opportunity’ for a considered re-evaluation of the Community’s health policy role. The primary reason for this is the nature of its revised content, recalling the sudden and specific addition of scope for Community action in phytosanitary and veterinary fields, as well as in the area of blood and human organs. This has led to a widespread view of the Article as a ‘knee jerk political reaction to the BSE crisis’ (97) (98), and has been attributed to last-minute lobbying by the Dutch delegation. In addition, the new Treaty did not address the basic need for institutional reform for the easier development and integration of health considerations into Community policy-making. Even the former Social Affairs Commissioner Flynn was quoted as saying “I must confess to a certain degree of disappointment on the text... Yes, the draft Treaty does confer new Community competencies in the field of public health. However... in my view, the new Treaty provisions do not provide the Commission with an adequate legal basis to address future concerns.” (99) This has also been echoed elsewhere 91, (100). So while the Amsterdam Treaty, and Article 152 specifically, did result in new Community competencies, some blame for the failings outlined above must be directed at the Member States’ health ministers who were in office during the IGC. They should have done much more to ensure that health policy concerns were fed into the policy-process, not only in creating the new Treaty, but more so during the preparation period preceding the IGC itself.

In summary, therefore, the Amsterdam Treaty and Article 152 do not outline a clearer and deeper role for the Community in health policy. Yet, this should not come as a surprise given the intergovernmental nature of Community decision-making and, as outlined in the earlier theoretical discussion, the lack of Member State interest in establishing EU authority in the field. Rather than signifying a pro-active Community role, the revision of Article 129 to 152 is a clear result of externalities forcing intergovernmental agreement on health issues. Health policy only came to the IGC table because of the BSE crisis; which in turn prompted both the Treaty change, along with the limited nature of the revision of Article 129.

**EU policy making: a synopsis**

It is important to recall that the driving force of the European integration process has been the establishment of a single market based on the institutional structures to support this development. Thus, one of the main reasons why health policy competencies are not more developed at EU-level - or at least have evolved in the manner they have done - has to do with the institutional construct of the Community decision-making process. The development of competencies, except where they relate to the requirements of the single market - such as pharmaceuticals, medical devices and the free movement of medical professionals- is framed by a decision-making structure that was originally designed with other purposes in mind. The most recent example is the establishment of the previously-mentioned European Medicines Evaluation Agency. As a quasi-regulatory body, the first of its kind in the EU, its mandate covers market authorisation issues for new pharmaceutical products being launched on the European market, but not matters pertaining to pricing and reimbursement. This construct reflects the economic and political imperatives that have driven the Community to-date, and a brief summary of the roles of the institutional actors involved in the EU policy-process elucidates this point quite clearly.

The European Commission, the European Parliament and the Council of Ministers are the principal actors responsible for devising and implementing policy in the EU. The Commission instigates policy, the Parliament considers the Commission’s proposals (and may amend or veto them), while the Council, via one of several voting procedures, also amends them and decides if and
when they should become law. This seems a straightforward enough configuration, but the procedural aspects assumed within this tripartite structure ensure that the process is a difficult one. Where policies relating to health policy (or other sensitive national issues) are concerned, the process is further complicated because of the principle of subsidiarity.

The Commission’s role involves the proposition and adoption of proposals for Regulations, Directives and Decisions, and the issuing of Recommendations and Opinions. The first three are binding, while the latter two are not. A proposal is developed by the Commission services in draft form, with input from relevant experts and national representatives. It is then formally put to the Commission for adoption by the Commissioner of the Directorate-General with responsibility for that particular area. Proposals require the collective agreement by the entire ‘College’ of Commissioners before then being presented to the Council. In turn, the Council is required to consult the Parliament for its view before rendering a final decision. Proposals are also sent to the EU’s Economic and Social Committee (ECOSOC) which may deliver a non-binding Opinion.

In proposing legislation, beyond the Directorates-General which comprise it, the Commission is reliant on a number of secondary bodies for advice (via a system of committees). For health policy matters, it is most often the Health and Consumer Affairs Directorate that is involved in drafting proposals on behalf of the Commission. The Parliament also operates a series of committees, and usually refers health policy questions to its Committee for the Environment, Public Health and Consumer Protection. The Committee drafts a resolution on the basis of the proposal at hand – seeking additional advice from other Parliamentary Committees – which Parliament then debates before delivering an opinion to the Commission. This (necessary) reliance of the EU decision-making process on a multitude of committees is a structure known as comitology (101). This description serves to indicate the complexity of the EU policy-process and goes some way towards explaining the often lengthy delays involved in implementing policy decisions. It is likely that provisions in the Amsterdam Treaty relating to the role of committees that will increase further the complexity of the decision-making (102).

Although the Parliament has in the past been deemed ineffectual as a legislature (103) – leading to criticisms of the Community’s so-called ‘democratic deficit (104,105)– since the introduction of a procedure known as ‘co-operation’ under the Single European Act, the Parliament’s role has been expanded beyond simply recommending amendments to Commission proposals, to vetoing them. This veto is, however, subject to unanimity in the Council, and only following a failure by the Conciliation Committee (a committee proceeding to resolve Parliament-Council deadlock in a mutually acceptable manner) to agree a compromise arrangement between the Parliament and the Council over the former’s proposed changes.

The Parliament’s veto was strengthened by the Maastricht Treaty through the ‘co-decision’ procedure. Whilst ‘co-operation’ granted Parliament a second reading of Commission proposals, ‘co-decision’ gave it a third. The Parliament is thereby able to reject Commission proposals outright if, following no result in conciliation, a qualified majority vote is achieved during a third reading. Only in two cases to-date has the ‘co-decision’ procedure failed to render a decision; the first in 1994 pertaining to telephony, and the second in 1995 regarding a Commission proposal on biotechnology. This latter decision has since been reversed, with Parliament approving the revised proposal on May 19th 1998.

As highlighted earlier, the EU decision-making process is a lengthy and complicated one. Nowhere is this more the case than with respect to health policy matters. There are two main inter-related reasons for this. The first is that despite the Health and Consumer Protection Directorate having primary responsibility for health matters, Community health policy responsibilities are in fact scattered between the remaining Directorates-General (DGs) of the
Commission. Second, and the main factor behind this dispersion of responsibility, is that health competencies have primarily been developed with an eye to establishing the single market.

The earlier chronology of the development of EU legislative competencies in health policy served to indicate that the Community’s interest in health policy, as a specific policy area of its own, did not feature until the Maastricht Treaty in 1992. Even then, however, it was not clear as to exactly what role Article 129 conferred upon the Community in policy-making terms (106); especially in light of the Community's focus on the single market. Specific areas in which the single market has impacted on health include increasing competition (107), the standardising of liability for medical services and private health insurance (108). The result has been the ad hoc development of EU powers alluded to earlier (109). The multitude of individual Community initiatives do not reflect a coherent health policy strategy.

Although few of the other DGs exercise executive powers with respect to health policy per se, the activities in which they engage can, and do, impact on health policy in a variety of manners. As was observed prior to Maastricht, “In sum, health is an EC-policy of minor priority, and selected aspects are scattered in various Directorates-General.” (110) Continuing with this dispersion of health powers, a survey prior to the 1999 reform of the Commission has shown that of the old 24 DGs, at least 16 had a significant involvement in matters related to health policy.

**Conclusion**

Although this chapter has considered European integration only superficially, it has served to contextualise health policy in a wider European framework. Although neither the theories nor the processes referred to were developed to explain specific policy developments, aspects of both, at each level, are shown as relevant to the development of EU health policy competencies. In particular, the chapter has shown how the ECJ has played a major role in raising health policy issues and how it has become a major contributor to the development of EU health policy.

This chapter also emphasised that the current system for developing EU health policy (the new DG for Health and Consumer Protection notwithstanding), as it has evolved since the Treaty of Rome in 1957, is no longer appropriate for dealing with contemporary health policy challenges (if, in fact, it ever was). There is no all-encompassing strategic health policy and there is a need for a new Community health policy. It must be one that has at its foundation a new and comprehensive Treaty-based definition of health policy and the EU’s role therein, and one that takes into account the wider determinants of health and disease as well as an agreed position among Member States on what they are seeking to achieve through their health care systems.

In the next chapters we begin to assess the main implications of EU law for certain key elements of health policies.
CHAPTER 3: FREE MOVEMENT OF PROFESSIONALS

Introduction

Health professionals have a privileged position. They are entrusted by the state with certain rights denied to others (such as prescribing in the case of physicians and, in some countries, nurses) and they have exclusive rights to be employed in certain positions. Conversely they also have certain responsibilities. As individuals, they must ensure that they continually update their skills and knowledge and they must adhere to certain ethical standards, in particular avoiding situations that might exploit their position in relation to patients. Collectively, health professionals play a major role in determining the scope and nature of professional training, establishing a framework for continuing education, monitoring the quality of clinical practice, and ensuring the application of high ethical standards.

These collective responsibilities are undertaken at the level of the Member State. The mechanisms employed vary considerably, reflecting historical differences in institutions involved (universities, government, professional organisations etc.) and the relationship between health professionals and the state. European law on movement of professionals is essentially blind to these differences, basing its provisions on the principle of mutual recognition. Once educational programmes comply with a basic standard, typically defined in terms of length of training, those completing them are assumed to have reached a level of competence that will enable them to work anywhere in the EU.

There are obvious benefits to be achieved from promoting free movement. The supply of health professionals across Europe is extremely uneven, with surpluses in some countries and shortages in others. The diversity of health care provision, while potentially a problem also offers many opportunities to exchange examples of good practice. However there are some concerns. First, there are widely held beliefs that qualifications from all countries are not equivalent, often with very different amounts of direct patient contact and resulting practical experience. This can act as a barrier to mobility as, although illegal, indirect forms of discrimination may be employed. Second, the rapid growth in health care knowledge means that someone qualifying even ten years previously will soon be out of date unless they have taken positive steps to keep abreast of developments. This has led some governments to introduce systems of revalidation, in which qualifications only remain valid as long as practitioners can provide evidence that remain fit to practice. However the whole area of continuing professional development varies enormously across Europe.

The challenge, therefore, is to find ways that promote free movement while at the same time promoting high standards of professional knowledge, both at qualification and throughout the individual's career.

The legal framework

While the Treaty establishes a general basis for free movement of health professionals, with Article 6 (ex 3(c) and Article 47.2 (ex 57.2) allowing for the co-ordination of rules regulating self-employed activities, health professionals have been recognised as requiring special attention. Article 47.3 (ex 57.3) states that ‘in the case of the medical and allied and pharmaceutical professions, the progressive abolition of restrictions shall be dependent upon co-ordination of the conditions for their exercise in the various Member States’. For this reason the medical and other health care professions were among the first to be subject to specific regulations at the EC level (111,112).
There are two ways in which professional qualifications can be recognised throughout the EU and two types of directives that establish the criteria for professional recognition:

- sectoral directives apply to certain professions such as architects, midwives, pharmacists, doctors, nurses responsible for general care, dentists and veterinary surgeons, and operate on the basis of mutual recognition of diplomas
- all other professions come under a general system of recognition of professions, which operates on the basis of whether a profession is regulated or not

In an attempt to facilitate the free movement of health professionals, the so-called ‘doctors’ directives’ 75/362/EEC113 and 75/363/EEC114 were adopted in 1975 and have been in force since early 1976, well before the establishment of the single market. These entitle doctors to full registration in any EU Member State if they fulfil the following criteria:

- they are citizens of a Member State
- they have completed primary training in a Member State and hold a recognised qualification

The first directive 75/362/EEC (113) deals with the mutual recognition of medical qualifications, which are broken down into three categories:

- diplomas, certificates and other evidence of formal qualifications in general medicine (Articles 2 and 3)
- those relating to specialised medicine common to all Member States (Articles 3 and 4)
- those relating to specialised medicine peculiar to two or more Member States (Articles 6 and 7)

Each Member State is required to recognise the qualifications listed in the directive by giving those qualifications the same effect in its territory as those that the Member State itself awards. Specialist recognition is more complex than recognition of primary training. If a doctor has completed specialist training in a specialty common to all Member States and which is included in the list in the directive (Articles 3 and 4), then he/she is entitled to be recognised as a specialist elsewhere in the EU. Specialties common to two or more Member States must also be recognised throughout the EU (Articles 6 and 7). However, these stipulations do not cover all specialties and the process of obtaining recognition for less common specialties can be very slow (112).

Directive 75/363/EEC (114) provides for the co-ordination of medical training courses. Member states are required to provide guarantees that during their training period individuals will acquire:

- adequate knowledge of the sciences on which medicine is based and a good understanding of the scientific methods
- sufficient understanding of the structure, functions and behaviour of healthy and sick persons, as well as relations between the state of health and the physical and social surroundings of the human being
- adequate knowledge of clinical disciplines and practices
- suitable clinical experience in hospitals under appropriate supervision

Where specialist training is concerned, minimum training periods are specified for each listed specialty.

A further directive 86/457/EEC (115) covers the requirements for general practice, although it did not take full effect until January 1995. Its aim is to correct the considerable imbalance between general practice requirements in different Member States.
Key features of directive 93/16/EEC

All three of these directives have now been repealed and consolidated, with various amendments for different specialities, in Council Directive 93/16/EEC (116). The main objective of directive 93/16/EEC (116) is to establish the minimum training requirements that are necessary and sufficient for the mutual recognition of medical diplomas. Beyond this, the organisation and content of medical training is largely the responsibility of individual Member States (as established in Articles 149-150 of the EC Treaty (ex Articles 126-127)). The directive also aims to establish rules regarding the exchange of information between Member States’ licensing / disciplinary boards about doctors who have provided substandard treatment due to carelessness, inadequate qualifications, mental health problems including the abuse of alcohol and other addictions.

Article 2 of the directive requires Member States to recognise the diplomas listed in Article 3 that have been awarded in accordance with Article 23. Article 23 states that medical training should comprise at least a six year course of 5,500 hours of theoretical instruction at university level. The directive also deals with specialised medical training (Article 24).

General practitioners

Since January 1990 Member States have been required to institute additional minimum levels of training. Since January 1995 doctors wanting to enter general practice in benefit in kind systems such as the National Health Service in the UK have had to complete a minimum of two years of vocational training, supervised by competent authorities and practical (rather than theoretical) in nature. This additional vocational training must include the trainee’s participation in professional activities and responsibilities for the persons with whom he/she works.

Specialists

The specialties listed in Article 5 are recognised by all Member States and holders of the relevant diplomas are entitled to automatic recognition whereas specialties listed in Article 7 are common to two or more Member States are automatically recognised by the Member States listed in this Article. Article 8 requires EU citizens coming from Member States which do not train in a specialty referred to in Articles 4 and 6, who wish to acquire a specialist diploma, to submit to the training required by the host state, subject to recognition of the training he/she has already undertaken.

Safeguards

The directive allows host Member States to request information regarding the good character or reputation of migrant doctors, if these characteristics are required of its own doctors (Article 11). An Advisory Committee of Medical Training (ACMT) was set up by Council Decision 74/364/EEC (117) to ensure that comparably demanding standards were maintained with regard both to basic training and further training. The Committee of Senior Officials on Public Health was also set up to adapt the directives to changing conditions, but the speed of change has made keeping the directives up to date a difficult task (111).

Directive 93/16/EEC (116) has recently been amended and is now the subject of further amendments. In 1998 the European Commission presented a legislative proposal to update various EU directives relating to mutual recognition of professional qualifications. The so-called SLIM directive, part of Simpler Legislation in the Internal Market initiative, aimed to include amendments to the doctors’ directive and those covering diplomas for nurses, midwives, dentists, vets and architects. In May 2001 the European Commission issued a further directive (2001/19/EC) (118) amending directive 93/16/EEC (116) and other directives concerning the...
professions of nurse responsible for general care, dental practitioner, veterinary surgeon, midwife, architect, pharmacist and doctor.

The directives in practice

If the single market provisions on health professionals are to bring tangible benefits to European health systems they must facilitate movement of such a scale as to redress the large inequalities in supply within Europe. There is little evidence that they have succeeded. Although health professionals may be better placed than others to transfer their skills from one country to another, the scale of movement within the EU has been extremely limited. Mobility of physicians has been studied most. For example, the United Kingdom, which is traditionally the largest importer of health professionals, in part because of the widespread use of the English language, has attracted relatively few doctors from elsewhere (119,111). In 1998, 411 doctors came to the UK from Germany, followed by 291 from Greece, and then Italy and Ireland, from which came with just under 200 doctors each (111). In the same year 219 doctors migrated to Greece (156 from Italy and 43 from Germany).

The failure of the doctors' directives to promote mobility has been attributed to cultural, social and institutional barriers (including the issue of language), and to the persistence of restrictive national policies (119,120). Not all Member States have implemented the directive in every area. In 2000 the European Commission referred the Netherlands, Ireland and Portugal to the European Court of Justice for failing to implement directive 98/21/EC, which amends directive 93/16/EEC(116) with regard to doctors specialised in occupational medicine. The Commission also sent reasoned opinion to the Netherlands, Ireland, Spain and Portugal for failing to implement directive 98/63/EC amending directive 93/16/EEC (116) by modifying the list of specialised doctors' diplomas that are recognised throughout the EU (EC 2000) (121).

A further problem is that mutual recognition directives only apply to diplomas obtained in EU Member States and do not cover those from a third country. This poses problems in countries such as the UK, where a significant number of doctors have qualified in non-EU countries (particularly the Indian subcontinent) but have had their qualifications recognised and approved by the GMC (the doctors' regulatory body). Most of these doctors have also obtained further qualifications in the UK. As their qualifications are recognised by the regulatory body in the UK, it is argued that they should be recognised by other Member States as well (112). New legislation is planned to commit registration bodies to take into account the experience acquired elsewhere of doctors registered and practising in the EEA, so that cases can be considered on an individual basis, although there has been opposition to this in some countries (112).

Implications for health care

As noted earlier, the medical directives simply set minimum training standards. Although these standards are enforceable, the somewhat loose way in which they are defined, based mainly on duration of training without addressing content, means that there is considerable variation in the scope and nature of training required in different Member States.

The issue of specialist medical training has particular implications for health services as trainee doctors are engaged in both training and health care provision roles. Historically, the duration of specialist training has varied considerably, with especially long periods in the UK and Ireland. Both countries have now reduced these periods but this has important implications for hospital staffing, in particular for smaller hospitals, which have long been dependent on a continuing flow of trainees who provide a substantial amount of medical and surgical care, especially at evenings and weekends. A reduction in training periods, accentuated by a shift from the service to the
training component, has threatened the viability of some hospitals, with implications for the geographical distribution of facilities. This will be accentuated once the Working Time Directive is applied to junior medical staff.

However the most important implication of the directives is that health professionals meeting the minimum standards set out in the directives are deemed to be of adequate quality to practice. This view has most recently been endorsed by the ECJ which, in Kohll and Decker, asserted its belief that the mutual recognition directives are sufficient to ensure uniform care across the EU. In Decker, the Court famously argued that ‘the purchase of a pair of spectacles from an optician established in another Member State provides guarantees equivalent to those afforded on the sale of a pair of spectacles by an optician established in the national territory’ (Decker, paragraph 43). This Court’s basis for this decision has been heavily criticised as being the wrong legal basis on which to assume that there is a similar standard of health care across the EU (122).

This raises several unresolved issues, the importance of which is growing as more patients are treated in other member States and, in particular, where health authorities and sickness funds contract with providers in another member State. Formally, the legal position is clear, in that those contracting with providers cannot impose conditions that are directly or indirectly discriminatory. This means that health professionals in other Member States must comply with any systems of continuing professional development and revalidation that are in place in the first Member State. However, this means that those health professionals engaging in such contracts may have to comply with several different regulatory regimes, with the consequent financial and time costs.

A further issue arises where a health professional who has either failed to be revalidated in his/her own country or has been erased from the relevant professional register. While there are systems, albeit imperfect, in place to address the second issue, it is entirely possible that an individual may be permitted to practice in another Member State but not their own.

These issues were explored at a symposium organised by the Dutch Ministry of Health, Welfare and Sport in 1997, which expressed concern at the directives’ implications, particularly with regard to upholding standards and protecting EU citizens from harm caused by substandard medical practice (123). This symposium highlighted the numerous differences between Member States in the areas of education, authorisation and disciplinary and compensatory procedures. It also highlighted the problem some Member States face in keeping records of problematic health professionals and the issue of liability in cases where competent authorities were unable to enforce aspects of directive 93/16/EEC (116). It concluded the directive should be more stringent, particularly regarding the description of the content of minimum education, the need for continuous education, the establishment of national databases of doctors with ‘professional problems’ and the necessity of involving patients in the decision-making process.

In summary, the directives’ emphasis on promotion of free movement has been at the expense of consideration of how to ensure the continuing quality of the professionals involved. As Member States move from a model in which qualifying as a health professional entitles one to practice for life to one based on evidence of continuing professional development it will be necessary to incorporate explicitly issues of professional quality.
CHAPTER 4: FREE MOVEMENT OF PATIENTS

Patient movement across borders within the EU

This chapter reviews recent rulings of the European Court of Justice (ECJ) concerning the free movement of patients within the European Union (EU), and discusses the implications of these rulings for health and social care systems in EU Member States.

In theory, national boundaries do not exist for individuals seeking health care in another Member State of the EU, in so far as people are free to move and live anywhere within the territory of the EU, but because authorities responsible for health care usually confine their activities to their own country, statutory health coverage has traditionally been limited to providers established within national boundaries. This is known as the territoriality principle.

Since 1958, the EC Treaty provides an exemption to the territoriality principle in order to encourage the free movement of people within the EU. The Community mechanism for the coordination of social security systems, based on EC Regulations 1408/71 and 574/72, has allowed migrant workers and their dependant family members residing in another EU Member State to receive health care in their country in which they reside (124,125). These regulations were subsequently extended to virtually the entire EU population (with the exception of nationals from third countries, who are excluded from this system, even if they reside in the EU and are affiliated to a national social security system).

There are two grounds for eligibility for health care during a temporary stay abroad. They differ as to whether they incorporate the principle of “urgency”, in other words, whether their condition requires urgent investigation and treatment. Persons who may receive treatment regardless of whether their condition is urgent include:

- pensioners entitled to a pension or pensions and their families
- employed and self-employed persons in unemployment and their families who go to another Member State to look for a job
- employed or self-employed persons exercising their professional activity in another Member State
- frontier workers (although their families must obtain prior authorisation for non urgent treatment if there is no agreement between the countries concerned)
- students and those undertaking professional training and their families (since October 1997)

For all other persons, the condition of urgency of treatment should be met (under Article 22.1 of the EC Treaty). Access to health care outside the Member State of residence is therefore essentially limited to urgent health care during a temporary stay in another Member State (certified by form E111). Otherwise, those seeking planned health care in another Member State, under Article 22.1 of EC Regulation 1408/71 must obtain prior authorisation from the patient's competent social security institution (certified by form E112).

So far, however, these regulations have not resulted in widespread movement of patients, largely because Member States have generally taken a restrictive approach to health care provided abroad. In 1978 and 1979, two ECJ judgements relating to the conditions governing the granting of prior authorisation under Article 22 of EC Regulation 1408/71 established the principle that authorisation must be granted in all cases where it will improve the medical state of the patient, irrespective of any other considerations (the Pierik judgements (1978-79)) (126). This
interpretation forced the Council to restrict the scope of the relevant regulation (127). Under the amended regulation Member States retain a wide discretion in defining their authorisation policy, as Article 22.2.2 only states when authorisation cannot be refused:

- when the treatment required by the interested party is part of the health care package covered by the social protection system in the area of health care
- and this treatment cannot be given to him in his State of residence within the period that is normally necessary, in view of his current state of health and the probable course of his disease

It has been argued that the second condition was put in place in order to prevent patients from bypassing waiting lists by seeking authorisation for treatment abroad (128), although this view could be contested on the grounds that waiting lists were not an issue in 1991. Consequently, Member States have generally refused to authorise any treatment in another Member State that can be provided in the original State. As Table 5.1 shows, even now, a country such as the UK only grants about 600 E112 forms a year, France some 200 and Sweden not more than 20. Belgium and Luxembourg have been somewhat less restrictive, relative to the size of their populations, issuing about 2,000 and 7,000 E112 authorisations a year respectively (129).

Table 5.1 The number of people seeking and obtaining prior authorisation for treatment abroad in selected EU Member States

<table>
<thead>
<tr>
<th>Country</th>
<th>Year</th>
<th>No of requests for authorisation</th>
<th>No of authorisations granted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>Each year</td>
<td>Na</td>
<td>850</td>
</tr>
<tr>
<td>Belgium</td>
<td>Each year</td>
<td>Na</td>
<td>2000</td>
</tr>
<tr>
<td>Denmark</td>
<td>Each year</td>
<td>40-50</td>
<td>25-35</td>
</tr>
<tr>
<td>France</td>
<td>1996-1999</td>
<td>1240 / 4 years</td>
<td>789 / 4 years</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>1998</td>
<td>7130</td>
<td>7082</td>
</tr>
<tr>
<td>Sweden</td>
<td>Each year</td>
<td>Na</td>
<td>20</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>Each year</td>
<td>800</td>
<td>600</td>
</tr>
</tbody>
</table>

Source: Palm et al., 2000

This reluctance on the part of Member States to support greater patient movement partly explains the marginal financial impact of EU cross-border care on public budgets; on average each Member State spends approximately € 2 per inhabitant, representing less than 0.5% of public expenditure on health care.

However, other, more natural, obstacles also stand in the way of receiving treatment abroad, such as language, distance, lack of information about the type of health care provided abroad, unfamiliarity with a different health care system, the unwillingness of local doctors to refer patients to other countries, the administrative burden of the procedures involved and travel time and costs (130). The demand for cross-border health care appears to be concentrated in border areas (or very small states like Luxembourg) and often involves high technology health care. It also concerns a limited group of people, in particular those with access to sufficient information (131). But even in the cross-border ‘Euregios’, where the potential for cross-border health care is greatest, or between Northern Ireland and the Republic of Ireland, where patient movement is being promoted as part of the Irish peace process (132), there is a lack of adequate information available to potential cross-border patients (133). The practical and legal obstacles to cross-border care are likely to remain considerable for some time (134). Nevertheless, the demand for cross-border care will almost certainly increase in future, as the experience of the ‘Euregios’ shows(134), and as evidenced by the various claims before national courts and the ECJ,
as well as by growing public interest in this issue. Several factors may further stimulate this demand, including: the increased movement of people in general; increasing shortages of human and financial resources creating waiting lists and other access problems; the development of new experimental treatments in some Member States; increased information among patients; growing integration in border areas; the increased ability to compare prices due to monetary union; the possibility of distance selling (see chapter 8); and the likelihood of further claims before the ECJ, in the light of recent rulings (see below).

Patients are likely to be supported in their efforts to become more active consumers in a European health care market: first, by health care providers, who are better informed about the health services offered in other health care systems and are seeking to stake their own positions in this market; second, by health insurance bodies seeking to offer the best health services to their clients at the lowest cost; and third, by politicians and the media, seeking to raise awareness of differences in levels of provision as a means of pressuring low-spending states to increase expenditure. These groups could play an increasing role in encouraging patients to undertake treatment in Member States other than their own.

**The rulings of the European Court of Justice: a turning point?**

**The Kohll and Decker rulings of April 1998**

Discussion about access to health care abroad has traditionally been based on the principle of free movement of people within the EU, but in 1998 the ECJ was required to assess the rules regarding access to health care abroad in the light of the free movement of goods and services.

The Kohll and Decker rulings of the ECJ concerned two persons insured under the Luxembourg social security system who had obtained orthodontic treatment in Germany (Raymond Kohll) and spectacles in Belgium (Nicolas Decker) and wanted to be reimbursed by their health insurance fund in Luxembourg, even though the fund had not previously authorised their treatment abroad (135), (136). Decker did not ask for prior authorisation to buy spectacles in another Member State, as was required by Luxembourg’s regulations, while Kohll requested authorisation but it was refused on the grounds that dental treatment in Germany was not considered to be urgent and therefore could have been provided in Luxembourg. Kohll argued that the prior authorisation procedure restricted him from purchasing services in other EU Member States and therefore contravened Articles 49 and 50 (ex Articles 59 and 60) of the EC Treaty. Decker argued that the prior authorisation procedure restricted the free movement of goods within the EU and therefore violated Article 28 (ex Article 30) of the EC Treaty.

The Luxembourg government, joined in the proceedings by several other governments, initially argued that the rules on the free movement of goods and services did not apply to matters of social security because they were economic rules. After reviewing its case law in this area, the ECJ concluded that although Member States had a wide degree of discretion in organising their social security systems, the rules of those systems were not exempt from the rules on the free movement of goods and services. In his opinion, the Advocate General stated that the Court’s consistent view was that ‘Community law does not detract from the powers of the Member States to organise their social security systems’, but that this by no means implied that ‘the social security sector constitutes an island beyond the reach of Community law and that, as a consequence, all national rules relating to social security fall outside its scope’. He thus made it clear that Member States must comply with Community law when exercising their right to decide how to organise their social security systems.
In refusing to reimburse Kohll and Decker for the treatment they received abroad, the Luxembourg government had relied upon the national rules incorporating EC Regulation 1408/71 into Luxembourg law. The government justified its reliance on these national rules by arguing that prior authorisation was necessary in order to:

- ensure the financial balance of the social security system and to enable the government to provide a balanced medical and hospital service open to all insured persons
- protect the public health of the population since there would be no way of ensuring the quality of the goods and services provided by orthodontists and opticians in other Member States
- enable the government to provide a balanced medical and hospital service open to all insured persons

The Court dismissed all of these justifications.

- Since both Kohll and Decker only requested reimbursement according to national Luxembourg tariffs - instead of the tariff of the country of health care delivery as required by the challenged provisions - the Luxembourg health insurance fund would not have to pay more as a result of the transactions taking place abroad. Therefore there was no adverse impact on the financing of the social security system.
- The Court also dismissed the Luxembourg government's second argument concerning the quality of care provided by health practitioners in other Member States. Referring to the mutual recognition of diplomas and efforts made during the 1970s to harmonise training requirements for most medical professions (see, for example, Directive 93/16/EC (OJ 1993 L165 p1) which is a consolidation of all mutual recognition legislation for doctors, specialised doctors and general practitioners), the Court claimed that ‘the purchase of a pair of spectacles from an optician established in another Member State provides guarantees equivalent to those afforded on the sale of a pair of spectacles by an optician established in the national territory’ (Decker, paragraph 43). This argument has been heavily criticised on the grounds that it cannot be assumed that there is a similar standard of health care across the EU (137). In addition, the Court’s assumption appears to contradict emerging EU initiatives on accreditation and revalidation137. In fact, the rules on mutual recognition were originally introduced to facilitate the freedom to provide services, but have since been used to ensure the free movement of goods (138).

- Finally, the Court only would accept the argument for protection of each Member State’s own medical infrastructure if it could be shown that public health really would be really threatened, which it could not in this case.

The ECJ concluded that, by requiring prior authorisation, Luxembourg’s national rules had created an unjustified impediment to the free movement of goods and services within the EU. In Decker’s case, the Court applied the rules established in Dassonville (139), finding that Luxembourg’s national rules ‘encouraged insured persons to purchase medical products in Luxembourg rather than in other Member States, and are thus liable to curb the import of spectacles assembled in those states’ (paragraph 36). In the case of Kohll, the Court found that ‘such rules deter insured persons from approaching providers of medical services established in another Member State’ (paragraph 35). As in the landmark rulings of Dassonville and Cassis de Dijon in the 1970s, in which the Court established the concept of direct or indirect, effective or potential, barriers to trade and to the freedom to provide services (140), merely showing that the free movement of goods and services might possibly be prevented was sufficient to be considered incompatible with the EC Treaty.
While Luxembourg’s national rules had complied with EC Regulation 1408/71, this regulation did
not and could not take legal precedence over the EC Treaty itself. The Court argued that although
EC Regulation 1408/71 was valid, it did not provide an exhaustive list of the means by which an
individual could obtain medical goods and services in another Member State, and should be seen
as merely one possible means.

Through the Kohll and Decker rulings, therefore, the ECJ appears to have established a dual
system of social protection for non-urgent health care received in another Member State, giving
EU citizens a choice of two options for coverage of health care abroad(129).

On the one hand, the ECJ upheld the classic E112 procedure governed by EC Regulation 1408/71,
in which the patient who has received prior authorisation from their social security institution is
accepted by the social protection system of the country in which they receive the medical
treatment ‘as though [they] were insured with it’ (Article 22.1.c). This implies that the patient is
subject to the same arrangements regarding, for example, cost-sharing and referral for specialist
care, and that any health care costs are settled between both social protection systems according
to the tariffs of the country in which the treatment was delivered.

On the other hand, the ECJ created an alternative (Kohll and Decker) procedure, based directly
on the EC Treaty, by which patients receiving treatment abroad without prior authorisation are
not integrated into the social protection system of another Member State, but can claim
reimbursement from their own social protection system ‘as if they received the treatment there’.
This would mean that reimbursement in the home state is subject to the conditions and according
to the tariffs applicable there.

The wider implications of the rulings, at the time they were made, were not clear, and much of
the political reaction that followed was fiercely defensive. Some saw the rulings as establishing an
important precedent with serious implications for the planning of health services and for cost
containment policies in health care, if the decisions were to be generalised.

Consequently, several official sources argued that in-patient care, having particular characteristics,
would not be affected. In fact, in Kohll’s case, the ECJ’s Advocate General stated that the
provision of orthodontic services did not interfere with the legitimate right of governments to plan
their hospital systems, and this was seen to preclude the application of the rulings to hospital
services129. In his opinion, the Advocate General noted that ‘unlike the benefits provided by
individual practitioners, the reality in the case of hospitals is, first, that their location and number
is determined by forward planning and, secondly, that the cost of one person’s stay in hospital
cannot be separated from that of the hospital as a whole. Clearly, if a large number of insured
persons chose to avail themselves of hospital facilities located in another Member State, their
domestic hospitals would be under-utilised but would have the same staff and equipment
overheads as if they were being used to full capacity’ (paragraph 59 of Advocate General’s
opinion). The requirement to maintain a balanced medical and hospital service to all might
provide a justification for discrimination in the future (although it did not do so in this case).

Some Member States also denied that the rulings had any consequences for their health care
systems on the grounds that the rulings only applied to systems operating on a reimbursement
basis (as with out-patient services in Luxembourg, Belgium and France), whereas their health
services were provided in kind through contracted providers via social insurance or a national
health system. Arguing that the second (Kohll and Decker) option for coverage of health care
abroad was not feasible in health care systems where there is no established reimbursement
mechanism, they maintained their traditional restrictive policy of authorising non-emergency
health care abroad only if medically required.
So, while the Kohll and Decker rulings made it clear that the EC principles concerning the free movement of goods and services could and would be applied to the realm of national social security systems, and that goods and services received by a patient in another Member State could be treated as if they had been delivered in the patient’s state of residence, they also led to confusion on two issues. First, whether they applied to hospital as well as ambulatory care and, secondly, whether they applied to all types of health care system, and not just to the reimbursement systems of France, Belgium and Luxembourg. Following the judgements of the ECJ, only Luxembourg, Belgium and Denmark amended their legislation and established administrative procedures for the unconditional reimbursement of certain out-patient services and health care products purchased in another Member State.

The Smits-Peerbooms and Vanbraekel rulings of July 2001

Subsequent cases brought before the ECJ in July 2001 provided further clarification of the Kohll and Decker rulings. Mrs Smits and Mr Peerbooms were both insured under the benefits in kind system of the social health insurance scheme in the Netherlands, where permission to obtain treatment from non contracted providers abroad is only granted if:

- the required treatment falls within the scope of what is regarded as ‘usual in the professional circles concerned’
- the required treatment is necessary and is not available without undue delay in the Netherlands

Mrs Geraets-Smits received multidisciplinary treatment for Parkinson’s disease from a specialised clinic in Germany without obtaining prior authorisation from her Dutch sickness fund, paid the clinic directly and then requested reimbursement from the fund according to the procedure set in place by Kohll and Decker. The Dutch sickness fund refused to reimburse her on the grounds that the treatment she had obtained was not ‘usual’, that satisfactory and adequate treatment for her symptoms was available in the Netherlands from a contracted provider and that the treatment provided in Germany conferred no additional advantage.

Mr Peerbooms went into a coma after a car accident at the age of 36. At the request of his consultant neurologist, he was moved to a clinic in Austria where he received intensive neuro-stimulation therapy and recovered full consciousness. In the Netherlands this therapy is only available on an experimental basis in two institutions and only to people under 25 years old, whereas it is fully covered by the social health insurance scheme in Austria. Mr Peerboom’s consultant requested reimbursement for the cost of the treatment but was refused on the grounds that appropriate care could have been obtained from a contracted provider in the Netherlands.

Mrs Smits and Mr Peerbooms initiated court action, claiming that they were entitled to a refund of the costs of their treatment under the EC rules on the free movement of services. The ECJ had to decide whether:

- the EC Treaty provisions on the free movement of services applied to health care provided in hospitals
- the requirement of prior authorisation for hospital treatment abroad violated these Treaty provisions

\* In Austria, even before the Kohll and Decker rulings, socially insured persons were entitled to reimbursement of health care from a non-contracted provider in Austria or abroad at a rate of 80% of the amount paid for the same treatment from a contracted provider (Palm et al 2000, ch3).
In *Smits-Peerbooms* and *Vanbraekel* (see below) the Court began by reiterating its consistent view, according to its own case law (143), that while Community law does not detract from the power of Member States to organise their social security systems, Member States must comply with Community law (and in particular with the principle of freedom to provide services) when exercising that power.

The Court then dismissed the argument advanced by several Member States that had joined in the action, that hospital services should not be regarded as services in the sense of Article 50 (ex Article 60) of the EC Treaty (that is, as an economic activity that is provided for remuneration), especially when they are provided in kind and free of charge (as opposed to through a system of reimbursement). By regarding them not to be “services” they would be exempt from many aspects of EU law (see chapter 3). The Member States argued that:

- there was no remuneration within the meaning of Article 50 when the patient received treatment without paying for it (as a benefit in kind) or where all or part of the amount paid was reimbursed
- in order to constitute an economic activity within the meaning of Article 50 (ex Article 60) the person providing the service must do so with a view to making a profit
- social security systems could not come within the sphere of the fundamental economic freedoms guaranteed by the Treaty because the persons concerned are unable to decide for themselves the content, type and extent of a service and the price they will pay

The Court did not uphold any of these arguments. Instead, it reaffirmed its view, on the basis of previous case law, that medical activities do fall within the scope of the rules on the freedom to provide services, and that there is ‘no need to distinguish in that regard between care provided in a hospital environment and care provided outside such an environment’ (*Smits-Peerbooms*, paragraph 53). The Court went on to note that Mrs Geraets-Smits and Mr Peerbooms did actually pay the hospitals that treated them directly, even though they subsequently applied for reimbursement, although the ECJ also noted that a service did not necessarily have to be paid for by the person receiving it, in order for it to be classified as a service. Because hospitals are paid for the services they provide, the ECJ concluded that treatment in a contracted or foreign hospital was a service in the sense given in the EC Treaty. Thus the Court confirmed that the alternative *Kohll* and *Decker* procedure, in principle, applies to all health care systems, whether based on reimbursement or on in kind benefits, and to all health services, in-patient and out-patient.

It had been established, in joined Cases 286/82 and 26/83 *Luisi and Carbone* [1984] ECR 377, that the freedom to provide services includes the freedom, for the recipients of services, to go to another Member State in order to receive a service there, without being obstructed by restrictions, even in relation to payments and that tourists, persons receiving medical treatment and persons travelling for the purpose of education or business are to be regarded as recipients of services (paragraph 16) (our italics). The *Luisi* and *Carbone* ruling was confirmed by the *Grogan* judgement, in which the Court clarified the economic nature of medical activities and found that medical termination of pregnancy constituted a services within the meaning of Article 60 of the EC Treaty.(144).

The Court found that the need to apply for prior authorisation for treatment abroad would deter insured persons from applying to providers of medical services established in another Member State and thus constituted, for insured persons and service providers, a barrier to the freedom to provide services. However, the Court stated that such a barrier can be justified in the light of overriding reasons in the general interest, such as:
• where there is a risk of seriously undermining a social security system's financial balance;
• where the objective of maintaining a balanced medical and hospital service open to all is jeopardised;
• where the maintenance of treatment capacity or medical competence on national territory is essential for the public health, and even the survival of, the population.

The Court found that, in such cases as they related to medical services provided within hospital infrastructure, prior authorisation could indeed be justified as a necessary and reasonable measure for guaranteeing a rational, stable, balanced and accessible supply of hospital services by means of planning and contracting. The Court recognised that 'medical services provided in a hospital take place within an infrastructure with, undoubtedly, certain very distinct characteristics. It is thus well known that the number of hospitals, their geographical distribution, the mode of their organisation and the equipment with which they are provided, and even the nature of the medical services which they are able to offer, are all matters for which planning must be possible' (Smits-Peerbooms, paragraph 76). It explained that planning and contracting were also necessary to avoid wasting financial, technical and human resources and to control costs. The Court therefore concluded that 'if insured persons were at liberty, regardless of the circumstances, to use the services of hospitals with which their sickness insurance fund had no contractual arrangements, whether they were situated in the Netherlands or in another Member State, all the planning which goes into the contractual system in an effort to guarantee a rationalised, stable, balanced and accessible supply of hospital services would be jeopardised at a stroke (Smits-Peerbooms, paragraph 81).

However, the Court made clear that such an exemption to the principle of the free movement of services was only acceptable if the system of prior authorisation proved to be necessary and proportional and was based on objective criteria that did not discriminate against providers established in another Member State.

As to the first condition, that the foreign medical service should be held to be 'usual' treatment, the Court noted that this condition also applies to medical services provided in the Netherlands. The ECJ noted that a Member State can define the scope of its own social security system and, consequently, can establish limited lists excluding certain products or services from reimbursement under its social security system, in order to contain costs. Community law cannot in principle require Member States to extend the list of medical services that are paid for by their social security systems (regardless of whether a particular type of treatment is covered by the social insurance schemes of other Member States). However, the package of benefits covered by social security must be defined in accordance with Article 30 of the EC Treaty; that is, defined according to 'objective criteria, without reference to the origin of the products' (Smits-Peerbooms, paragraph 89, based on Duphar and Others, paragraph 21).

Similarly, in order for a prior authorisation scheme to be justified, it must be based on 'objective, non discriminatory criteria which are known in advance, in such a way as to circumscribe the exercise of the national authorities' discretion, so that it is not used arbitrarily' (Smits-Peerbooms, paragraph 90). In addition to being based on fair, objective and transparent criteria, decisions to grant or refuse prior authorisation must be made within a 'reasonable time' and 'be capable of being challenged in judicial or quasi-judicial proceedings' (paragraph 90, Smits-Peerbooms).

Therefore, decisions about what is considered 'usual' within professional circles must be based on what is 'sufficiently tried and tested by international medical science' rather than just what is considered usual in Dutch professional circles (Smits-Peerbooms, paragraph 108). The Court added that 'to allow only treatment habitually carried out on national territory and scientific views prevailing in national medical circles to determine what is or is not normal will not offer those
guarantees and will make it likely that Dutch providers will always be preferred in practice’ (Smits-Peerbooms, paragraph 96).

Secondly, concerning the authorisation condition that the foreign treatment is necessary for the insured person, the Court noted that this condition also applies to non-contracted provisions in the Netherlands: if equally effective treatment cannot be obtained without undue delay from a contracted establishment, the patient can be treated by a provider who is not contracted with his or her sickness fund. The Court went on to state that this condition should be implemented in the same way for foreign providers as for non-contracted Dutch providers. In other words, Dutch sickness funds cannot favour non-contracted providers in the Netherlands over providers established in another Member State (Smits-Peerbooms, paragraph 107). But the Court made it clear that, once it had been established that treatment could not be provided in time by a contracted provider, Dutch sickness funds could not favour non-contracted Dutch providers over providers in other Member States (Smits-Peerbooms, paragraph 107). In order to determine whether equally effective treatment can be obtained without undue delay from a contracted provider, national authorities are required to ‘have regard to all the circumstances of each specific case and to take due account not only of the patient’s medical condition at the time when authorisation is sought but also of his past record’ (Smits-Peerbooms, paragraph 104).

Ms Descamps (Vanbraekel), a Belgian national insured under the Belgium social security system, requested authorisation from her sickness insurance fund to undergo orthopaedic surgery in France (145). In addition to the procedure established by Article 22.1.c of EC Regulation 1408/71, Belgian law provides for an alternative procedure based on Belgian reimbursement tariffs. Whereas the applied authorisation criteria under the Community procedure are rather strict (only what is covered but cannot be provided medically-technically in Belgium), the alternative authorisation procedure is more flexible:

- if treatment abroad can be provided under better medical conditions,
- and has been considered (prior to the treatment) indispensable for the patient (to be certified by a medical expert from a Belgian university hospital).

The Belgian authorities refused Ms Descamps’ request for authorisation because she had not obtained the opinion of an expert in a national university hospital. After obtaining treatment in France (without authorisation) Ms Descamps returned to Belgium and launched a successful appeal in the Belgian courts. Based upon an expert report, the courts agreed that she should have been given authorisation, because the restoration of her health did require surgery that could be performed under better medical conditions in France. However, they could not decide whether she should be reimbursed according to the Belgian or the French tariffs. Under the E112 system she would have been reimbursed according to the French tariff (FF38,608.99), whereas under the Kohll and Decker procedure she should have been reimbursed according to the Belgian tariff (FF49,935.44). Consequently, they asked the ECJ to advise on which course should be adopted.

Since Article 22.1.c of EC Regulation 1408/71 does not define the criteria for prior authorisation, the ECJ considered that those provided under the Belgian alternative procedure should also be considered to apply to the Community procedure. Therefore, if an insured person was incorrectly refused authorisation to receive hospital treatment in another Member State, he or she should be guaranteed reimbursement according to the rules applicable in the Member State of treatment (as indicated in Article 22.1© of EC Regulation 1408/71). Citing Kohll, the Court found that EC Regulation 1408/71 does not prevent the insuring state from reimbursing according to its own tariffs when they would appear to be more favourable (Vanbraekel, paragraph 36). The Court then went on to investigate whether such a “top up arrangement” would be necessary for the
free movement of services. It concluded that, if a patient would be guaranteed a lower reimbursement than if treated in his home state, this would deter, if not prevent him from looking to foreign health care providers (Vanbraekel, paragraph 45). Therefore, the Belgian authorities were required to grant the patient an additional reimbursement to compensate for the difference, as this could not be justified by any risk of jeopardising the fundamental objectives of the national health system.

**Issues raised by the ECJ’s rulings**

The *Kohll* and *Decker* rulings established clearly, for the first time, that the economic rules regarding the free movement of goods and services within the EU can be applied to social security systems. The Court of Justice, in *Smits-Peerbooms* and *Vanbraekel*, also successfully answered the two questions raised by *Kohll* and *Decker*. First, that hospital services are considered services in the sense of Article 50 of the EC Treaty and are not, therefore, exempt from the rules on the freedom to provide services. Secondly, that the *Kohll* and *Decker* rulings apply to all types of health care system, including systems that provide benefits in kind, and not just to reimbursement systems.

However, the recent rulings raise further issues, and we may have to wait for the conclusion of cases still pending to shed light on them. First there is the issue of definitions. Even if Member States retain the right to define the package of treatment that they will cover, the evolving case law clearly indicates an expectation of a European-wide consensus on what should be covered and what is deemed to be evidence-based. In the case of *Smits-Peerbooms*, the ECJ did not define what it meant by criteria based on ‘international medical science’ (rather than what is considered normal treatment in Dutch professional circles), presumably on the assumption that there is a common medical paradigm in Europe (and the rest of the world) (147). But this disregards evidence concerning the diversity of national health beliefs and treatment patterns (148).

The ECJ also failed to define ‘undue delay’, a vague term which might have very different meanings in different health care systems. In *Smits-Peerbooms* the ECJ stated that prior authorisation could only be refused if ‘the same or equally effective treatment can be obtained without undue delay’ from a contracted provider. It could be argued that the Court’s ruling in this instance goes beyond the minimum pre-conditions for treatment abroad set out in the Regulation (Article 22.2.2.), and that ‘undue delay’ can now be interpreted in the patient’s favour (as opposed to the national authority’s). According to *Smits-Peerbooms*, national authorities must now ‘have regard to all the circumstances of each specific case and to take due account not only of the patient’s medical condition at the time when authorisation is sought but also of his past record’. The Court does not specify what it means by taking due account of a patient’s ‘past record’, but giving citizens the right to challenge prior authorisation decisions in judicial or quasi-judicial proceedings seems to suggest that the Court is unwilling to tolerate blanket refusals on the part of national authorities.

The Van Riet case, in which a Dutch citizen received an arthroscopic intervention in a Belgian hospital instead of waiting for six months for the same treatment in the Netherlands, also addresses the highly topical issue of waiting lists, pertinent in several Member States (149). In this case the Court could clarify how far national discretion can go in limiting access to health care through delay mechanisms such as waiting lists.

The *Smits-Peerbooms* case confirmed a Member State’s competence to define the scope of medical services covered under a statutory health care system, but the Court warned that boundaries must be fair, objective, transparent and open to challenge. National rules that
explicitly exclude providers from other Member States will be outlawed and any rules that make it more difficult for providers from other Member States to participate in another Member State’s health care system will need to be justified, perhaps on the basis of providing sustainable health care for all or maintaining the financial balance of the health care system. The Court also noted a Member State’s capacity to draw up limited lists of treatment, which exclude certain products or services from reimbursement under its social security system, in order to contain costs. Nickless explains what effect this might have in practice. For example, allowing patients to attend any doctor in the country could be interpreted as allowing them to attend any doctor in the EU. Offering to reimburse emergency treatment provided by non-contracted hospitals in one country, when the patient’s condition prevents them from being taken to a contracted hospital, may also apply to non-contracted hospitals in other countries. When emergency treatment is provided under the E111 system, patients are treated as though they are insured in the state of treatment, which means that they would be taken to contracted hospitals and would have to pay any co-payments. The case of Müller-Fauré, in which a Dutch citizen deliberately requested dental care during her holiday in Germany, could reveal whether the priority given to contracted providers would also be upheld for ambulatory medical services. This case is important because of an increasing perception that provisions for emergency care (certified by E111) are actually being used to by-pass the restrictive policies with respect to non-emergency health care.

A further change brought about by the Vanbraekeel ruling concerns the additional reimbursement that Member States are now obliged to pay if their insurance would have provided a higher level of reimbursement than the country in which the patient received treatment. Nickless points out that this ruling goes beyond EC Regulation 1408/71; as with the Kohll and Decker rulings, the Court has considered the system established by the Regulation to be merely suggestive or non-exhaustive, thereby perpetuating the legal uncertainty. In this way, the ECJ amended the established E111 and E112 procedures by instituting a double guarantee of the most favourable coverage: the principle of equal treatment thus applies differently according to the respective levels of reimbursement in the home state and the treatment state. Finally, there are equity considerations, such as travel time and costs, making direct payments for treatment and proximity to borders. Under the Kohll and Decker procedure, travel and treatment costs must be paid directly by the patient, which raises the scenario of a two tier system in which wealthier patients are able to obtain unauthorised treatment abroad, while poorer patients or those living furthest from neighbouring countries, will have to use the existing system of prior authorisation (certified by E112). While the ruling sought to change the effect of the E112 procedure that prevented patients getting treatment abroad, this could continue where reimbursement is according to tariffs of one’s home state under the Kohll and Decker procedure where individuals live in countries with low medical tariffs. If governments are to make the most of these rulings by using them to ease waiting lists in their own country, this may be most likely to benefit patients living in relatively close proximity to the borders of another Member State, and governments would have to avoid creating a ‘postcode lottery’.

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9 It should be remembered that the ECJ, in its Ferlini ruling (ECJ, 3 October 2000, Ferlini, C-411/98), had already established the principle of equal treatment on the basis of nationality (Article 12.1 EC Treaty) for the application of medical tariffs, which were not considered as a social advantage (Article 7.1 EC Regulation 1612/68).
Conclusions

It would appear from these latest judgements that the ECJ has not only radically restricted Member States’ discretion to determine their own authorisation policies. It also seems to have changed rules of coverage under the classic social security co-ordination system. Consequently it seems that a revision of the legal framework regulating access to health care across the EU will be necessary.

The impact of the ECJ’s rulings extends beyond the sole scope of access to cross-border care. From the outset, the national authorities involved generally showed greater concern about the possible ‘internal effects’ on the organisation, operation and management of their health care systems, than about a massive outflow of patients. Besides the issue of waiting lists, they mentioned the risk of undermining measures aimed at containing costs and ensuring quality of care. National providers might consider national regulations being imposed upon them as distortions in comparison with foreign competitors. It should be noted that since the Kohll and Decker rulings were made, the Luxembourg authorities have not succeeded in concluding a new agreement with the Luxembourg medical profession.

The case law of the ECJ indirectly pits the possibility of extended choice for patients (at an EU level) against the principle of territoriality and Member States’ control over their social security systems. However, while Member States have raised concerns about the impact of the ECJ rulings on ‘medical tourism’ and governmental capacity for budgetary planning, expectations of significant numbers of patients crossing borders for treatment have not materialised. As yet the flow of patients across borders is relatively limited, and the demand for cross-border care continues to be constrained both by legal uncertainties and extra-legal factors.

As the ECJ rulings examined in this chapter have clearly prohibited any unjustifiable discrimination against health care providers established in other Member States, as a “side-effect” they could force national contracting mechanisms to be opened to all health care providers in the EU. In this respect it is important to recall that the ECJ previously declared European public procurement rules applicable to social security institutions contracting with service providers.

While awaiting further clarification from the European institutions, Member States should now develop a more proactive policy concerning cross-border access, integrating foreign supply into national health care planning and procurement. At a grass-roots level, some actors in the field of health care and social protection are already turning towards a European strategy and looking for less bureaucratic solutions that are better adapted to meet their needs and those of European patients.

Instead of emergence of what many see as a worst case scenario, with unregulated free movement of patients, European cross-border contracting could become an attractive means to improve access to health care while maintaining control over the cost and quality of care. This is not necessarily limited to border areas, where contracting across the border could complement a limited regional supply of medical services (during the last decade, initiatives and pilot projects have been developed in so-called “Euregions” to improve access to cross-border care in certain border areas essentially for the benefit of local residents, especially through promoting complementarity for existing medical services on either side of the border, in particular through the conclusion of bilateral agreements). It is also currently being explored by some countries seeking to ease existing waiting lists arising because of shortage of staff or other resources. It could also be used in tourist areas, where seasonal concentration of foreigners might justify contracting with a local provider that can offer culturally and linguistically appropriate facilities.
As rapid technological development seems to be leading towards more concentration and specialisation, European-wide planning of internationally renowned centres of excellence could offer a more cost-effective way of ensuring highly technical care in a few specialised areas. This necessary complementarity between people seeking treatment and facilities capable of treating them is an important part of the European integration process, in particular for achieving the EU goal of a minimum level of social cohesion. The process of enlargement highlights the efforts that must be made to bridge the gap in health status of Europe's citizens. In this respect, it should be reminded that the Charter of fundamental rights of the European Union, declared at the recent Nice Summit, contains a right to medical treatment “under the conditions established by national laws and practices” (art. 35).

The creation of an internal health care market and the further development of cross-border purchasing of care, will undoubtedly bring about the need for a kind of European reference framework providing benchmarks as to quality standards, equivalence of medical practice, licensing and accreditation, and patient rights. The ECJ was criticised on this point when it stated in Kohll and Decker that comparable levels of quality of care are sufficiently guaranteed through the system of mutual recognition of diplomas in the medical professions (152).

A note of caution is required. It will be necessary to ensure that further health care integration does not increase social inequalities in access to care. Wealthier and better informed citizens will be most likely to benefit from the extended rights to health care abroad. It is thus important that the creation of a European health care market does not weaken national health policy goals on equity. This is anyway a general obligation for all Community policies.

These issues can only be addressed adequately at the European level. In this context, the latest Community strategies on concerted action in the fields of social protection153 and public health154 could provide for the necessary instruments.
CHAPTER 5: PHARMACEUTICALS AND MEDICAL DEVICES

The changing regulatory environment

Over last ten years the general approach by which both pharmaceuticals and medical devices have been regulated in the EU has been changing. The requirements of the Single European Market (SEM) have prompted much action to harmonise national requirements and systems. The European Commission and, to a degree the two industries involved, have played the role of ‘policy entrepreneur’ in pushing this agenda. But the European Court of Justice (ECJ) has also been involved, helping clarify outstanding issues and technical matters where necessary. Further, the move towards the international harmonisation of regulatory requirements in both industries is beginning to affect the manner in which products are developed, marketed and sold. International rules for medical devices via the Global Harmonisation Task Force (GHTF) and, for medicines, through the International Conference on Harmonisation of Technical Requirements of Pharmaceuticals for Human Use (ICH), are becoming more encompassing and streamlined. There is also a concerted Europe-wide effort to reduce the duplication of effort and delays in market authorisation. Member State and supranational policy-makers alike are having to reshape current regulations and devise new ones that conform to the changing environment. This push towards homogeneity of guidelines under international regimes is, of course, a pattern mirrored in other non-EU countries as well.

The expanding role of the Community in the two sectors, and the increasing Europeanisation of the markets and their regulation, are the result of two complementary processes that contribute to the wider European integration dynamic. The first is the growing regulatory function of the Community, and the second is the expanding scope of European law. The former, which has been widely acknowledged by analysts seeking to explain its role in policy-setting, has evolved predominately from the single market programme. Meanwhile, the latter is mainly the result of gaps that have developed with respect to the application of the SEM in practice. Though both are therefore relevant to understanding how European law for pharmaceuticals and medical devices affects national health care systems, the discussion here concentrates on the latter.

This section examines the part played by European law and the European Court (both the Court of First Instance and European Court of Justice) specifically, in terms of ‘Europeanising’ policy for pharmaceuticals and medical devices. In so doing, it considers the implications of this process for national decision-makers vis-à-vis their health care systems; particularly in terms of the effect on the national policy environment. Nonetheless, as the two go hand-in-hand, a brief look at both is first necessary.

Community Regulation and European Law - some initial remarks

In academic circles, the concept of the Community as a ‘regulatory state’, one that makes rules and regulations to create a level playing-field for the fifteen Member States, has been proposed. This involves ‘creeping’ European competencies and implies a re-shaping of the national context. It generally represents a voluntary rescinding of powers by the Member States and the transfer of regulatory responsibilities upwards to the European level. In other words, it is an intentional de-regulation at the national level. The expansion of the Community’s regulatory function is thus partly the result of instances where national governments either feel the European arena is the more appropriate one in which decisions should be made or where the EU may be better placed to regulate, as well as reflecting concerns about which governments are willing to co-operate. Despite the explicit exclusion of health care matters from the Community’s competencies under the Amsterdam Treaty, the single market’s regulatory function has spilled into health care and other social policy areas (155). The Community regulatory function in respect of product
authorisation first appeared in 1965 but the process has subsequently deepened reflecting the development of the single market.

European law, meanwhile, also affects national rules and policy in a variety of ways, particularly through rulings delivered by the European Court of Justice. By insisting that national legal systems comply with European dictates, the development of European law complements the regulatory function of the Community. From simply taking away some responsibility from national decision-makers, to being integrated in full into national legislation, it impacts on Member States’ health (care) policy and systems.

As noted in the previous chapter, the ECJ’s ‘constitutional’ role in establishing European law as a *sui generis* system has thus had a major role in advancing integration in Europe generally (156), and promoting the evolution of a European health care policy more specifically (157). And while the Court has at times been accused of undue judicial activism, ECJ decisions are sometimes said to impinge on the decision-making sovereignty of the Member States by underlining both the principle of ‘direct effect’ and the ‘doctrine of supremacy’ of European law, it essentially plugs the holes left where national and EU legislation are discordant. In addition, it clarifies any outstanding issues relating to the completion of the single market. In the case of pharmaceuticals and medical devices, these gaps have to do with the clash between the principles of subsidiarity and the free movement of goods and services as enshrined under Article 28 (ex 30) of the Treaty. As the Court also fills in the gaps where the harmonisation of national provisions are concerned, it has undoubtedly helped establish the working rules of the Single European Market framework. Much of this legislation and the Court’s interpretations are therefore as relevant to health care as other areas.

Together, the continuing development of Community regulatory competencies and European law are promoting the ‘Europeanisation’ of policy on medicines and medical devices in the EU. In practice, there are two main dimensions to the process. The first is the issue of market authorisation and the Community’s attempts to harmonise and standardise, at EU-level, guidelines and approval procedures that fulfil health and safety criteria while meeting the interests of the main stakeholders in an equitable manner. These stakeholders are the Member States, the European Commission, consumers (patients) and the relevant industries. The second is the question of facilitating the free movement of products within the internal market, especially in terms of competition and industrial property rights issues. The two are unquestionably bound together. Although they represent different elements of the pursuit of harmonisation, they are both tied to the Single European Market programme. As the influence of European law is, of course, not limited to these areas, the paper also looks at other relevant questions such as the pricing and reimbursement of pharmaceuticals – most notably the divisive matter of parallel trade – and intellectual property rights, where the ECJ has had an especially prominent role and continues to set precedents.

‘Europeanising’ medical devices and pharmaceuticals

Both industrial policy and regulation of the Community’s pharmaceutical and medical devices sectors remain shared competences between the Community and the Member States. The reasons are widely documented and are too extensive to be detailed here. Briefly, the level at which regulation is carried out depends on whether one adopts an industrial or health policy

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h Respectively established in Case C-26/62 Van Gend en Loos v. Nederlandse Administratie der Belastingen (ECR-1), and Case C-08/64 Costa v. ENEL (ECR-585), direct effect means that Member States must directly enforce European law that is clear and precise enough to require no implementing legislation on the part of the Member States; and the doctrine of supremacy established the precept that, in the event of conflict, national law was to cede to European law.
perspective. Industrial policy is underpinned by wider harmonisation powers than health policy, but they both exist concurrently. What should be noted, however, is that despite this potential conflict, the continuing development of European competencies in both fields means that policy is increasingly being decided at the supranational level.

The EU regulatory frameworks for medicines and medical devices are vastly different. The former has a relatively long history dating back to 1965 when the first piece of Community pharmaceutical policy, Directive 65/65/EEC, was passed in the wake of the thalidomide tragedy. Its development has been driven largely by the requirements of the single market, though numerous pieces of Community legislation did in fact precede 1992. The latter framework is younger by some twenty-five years, having begun formally in 1990 with the Active Implantable Medical Devices Directive (AIMDD, Directive 90/358/EEC) as the first legislative measure in the field. Indeed, until the late 1980s there had been very little discussion about device regulation at EU-level. It was only with the prospect of the Single European Market that national policy-makers first came to recognise the need for a European framework. Since then the development of a politically and economically acceptable regulatory approach has followed relatively quickly. It has been driven primarily by the French, German and British ministries of health, with the support of the industry; both the leading individual companies (European and American) and the trade organisations (158). Thus, unlike medicines, the initial push for a Community medical device framework originated in pressure to enhance cross-border trade, rather than as the result of a specific public health concern. That said, health protection concerns have featured more prominently in subsequent years (158).

**Two incomplete frameworks**

The Community's pharmaceutical framework consists of some twenty pieces of EU legislation, both Directives and Regulations (which are binding measures). Its development has been somewhat *ad hoc*, reflecting the lack of a long-standing pan-European strategy for regulating the sector (159). This is largely due to the clash between the principle of subsidiarity on the one hand (political and tied to health care), and the requirements of the single market on the other (legal and pertaining to free movement). It is compounded by the European Commission’s interest in maintaining a strong and successful industry (particularly *vis-à-vis* the US and to a lesser degree Japan), and its push for greater harmonisation of national systems. The result is that, despite a host of competencies relating to industrial policy and promoting the single market, the market remains incomplete because pricing and reimbursement of medicines remain national concerns.

In comparison, the medical devices framework consists of only three Directives: the earlier-mentioned Active Implantable Medical Devices Directive; the broader ‘catch-all’ Medical Devices Directive (MDD, Directive 93/42/42/EEC) and the In Vitro Diagnostics Directive (IVDD, Directive 98/79/EC). Between them they establish the rules of the European regulatory system. In so doing they also define the specific roles of the Commission, the Member State governments and the so-called ‘notified bodies’, which are the public or private groups that act as the review and approval organisations for new devices. The system places public health protection at its heart, but it has unquestionably been designed to promote internal market goals in the first instance (160).

**Similar goals, different regimes**

One reason as to why medical devices legislation and policy have trailed pharmaceuticals is that the term ‘medical device’ covers a huge range of treatments from simple tongue depressors and orthotics to more complex implantable equipment such as cardiac pace-makers. In addition, the terminology also differs among Member States. Medicines are a more straightforward product in
terms of what they are designed to do, and were defined in a Directive as long ago as 1965. Another point of differentiation from pharmaceuticals – notwithstanding differences between the ethical, generic and over-the-counter sub-markets – is that there is no single medical device industry. According to Altenstetter, “Instead, there is a cluster of producers that can be subdivided roughly into four sectors: (i) medical-electrical devices; (ii) non-electrical products; (iii) implantables; and (iv) diagnostic products.” (161) The companies producing these goods are often not especially health-focussed. With the MDD, however, the EU has been able to establish a working definition of a medical device, which will allow for increased harmonisation of national standards and regulatory regimes in the future.

Part of this regime involves post-marketing surveillance mechanisms to enhance product safety. For medical devices these can be divided into two categories: performance tracking or ‘vigilance’ which is the duty of the manufacturer, and ‘product field performance’ which is an EU function. The two are separate but concurrent, and ideally, mutually-reinforcing processes. Manufacturers are obliged to report all adverse events associated with their products to their competent national authority (in the US this reporting is to the Federal Drug Administration). The Member States are themselves required to institute measures to gather and assess information derived from such reporting. On the basis of the information collated, the national authorities may then act to withdraw or simply restrict the (further) marketing of any devices found to have such adverse effects. Thus, going beyond pharmacovigilance for drugs, responsibility for medical devices lies not just with the manufacturer, but extends to national health care professionals and health care systems. In turn, the Member States must pass on the details of their actions to the European Commission, which reviews the action, ultimately sanctioning or overturning it. An important difference between the American and European regimes should be noted. While American reporting includes serious injury attributable to the device, EU reporting is limited to events involving death.

It should also be added that where medicines are concerned, the principles for product approval were also laid down in the original Directive, and that these have been at the heart of all EU pharmaceutical policy since then. In comparison with medical devices, therefore, pharmaceuticals are a far more consolidated area of Community competence, even if a single medicines market does not yet exist. The device regime is still evolving and is subject to a much greater reliance on national regulation.

**Market Authorisation**

The Single Market programme is the basis upon which the Community has been able to act, and indeed take over aspects of medicines and medical device market authorisation in the EU. The pursuit of market integration and the harmonisation of national rules and regulations has seen the EU develop a host of competencies. For pharmaceuticals this includes policy on labelling and packaging (Directive 92/27/EEC), advertising and sales promotion (Directive 92/26/EEC), and wholesale distribution (Directive 92/25/EEC), all of which reflect priorities of the single market. With a centralised European medicines office since 1995, the European Medicines Evaluation Agency (EMEA), even some elements of market approval have been taken out of the hands of national regulators.

This is not the case for medical devices where a so-called ‘Euro agency’ does not exist, and where market authorisation is not as strictly regulated. Rather than having to pass the so-called ‘public health test’ and meet the ‘three hurdles’ of quality, safety and efficacy to which medicines are subject before being granted market approval, medical devices are instead simply required to carry the CE Mark (Conformité Européen) signifying their conformity with the standards requisite for sale in the EU.
Medical Devices: The CE Mark

Following much negotiation amongst the Member States and the industry, the CE Mark established by means of the Medical Devices Directive. The idea was to create (harmonise) common technical guidelines that would be recognised by all Member States. This also involved device certification and an inspection process for manufacturers, so as to ensure safety and product quality. All new medical devices must now carry this seal of approval in order to comply with European law.

The CE Mark became operational in 1998 with all fifteen countries having enacted it into national law. There are, however, remaining problems with the system as the transposition of the CE Mark legislation differs among Member States. Some have simply written it into their own law books virtually verbatim, whilst others, generally those with expansive systems of their own, have instead adapted their own rules to accommodate the European legislation. Such differences mean that the new regime is still somewhat incomplete. This is compounded by the fact that the European Free Trade Area (EFTA) countries are also part of the CE Mark regime, and their legislation in matters pertaining to the single market is of course even more diverse than that of fifteen EU Members.

Unlike the strict independent regulatory approval procedures for medicines, the CE Mark for medical devices serves to indicate the manufacturer's own judgement that the product meets certain minimum standards. These are the 'essential requirements' laid down for the specific category of product. The list of essential requirements for each category covers a multitude of areas, including: “... safe design and construction, clinical efficacy, disclosure of residual risks, protective packaging, infection control, compatibility with other devices, calibration and stability, radiation protection, electrical safety, labelling and instruction manuals.” (162) Furthermore, the CE Mark indicates that the product is fit for its intended purpose and can, therefore, be freely marketed in the European Economic Area. In emphasising product standards and self-regulation, rather than involving government regulators (as is the case for medicines), the CE Mark regime is thus designed to facilitate the single market. Its aim has clearly been to facilitate intra-Community trade in medical devices, perhaps reflecting lessons learned from the difficulties encountered with the medicines system.

According to some analysts, this has meant that, without compromising safety, approval of new medical devices in Europe takes approximately half the time required in the US market; where the Food and Drug Administration (FDA), as for medicines, is the regulatory authority (163). The United State General Accounting Office (GAO) put the difference between the American and EU systems down to different regulatory requirements: “Devices marketed in the EU are reviewed for safety and performing as the manufacturer intended; devices marketed in the United States are reviewed for safety and effectiveness. Effectiveness includes the additional standard of providing a benefit to patients”. (164) The impetus for the GAO report came primarily from the American device industry and its perception that the then-emerging European system was more efficient160. The manufacturers asked whether the FDA should therefore adopt aspects of the EU regime. Although the GAO's findings were that it was premature to change, it does seem that time to market is indeed quicker in Europe. The CE Mark system has thus helped to promote the European industry in a high-technology sector where the US is otherwise dominant.

Pharmaceuticals: The European Agency for the Evaluation of Medicinal Products

Concerning market authorisation for medicines, undoubtedly the most important development was the establishment in 1995 of the EMEA. Created under Regulation 2309/93/EEC, the agency
occupies a unique place in the EU framework. It is the first, and as yet only, independent Community office exercising a real regulatory mandate. Rather than simply gathering and disseminating information, the EMEA proposes decisions that, if endorsed by the Commission, create Community policy and are binding on Member States. By means of its centralised and decentralised procedures, it proposes to the Commission decisions on market approval for new medicines, including those derived from biotechnology. Its assessments are based on the Community's safety, efficacy and quality criteria, first established under Directive 65/65/EEC.

The impact of the EMEA cannot be under-stated. Greeted as 'a real European milestone' by at least one analyst (165), the European Commission regards it as "... an important part of the overall strategy of the creation of a single market for pharmaceuticals" (166). The reason for such applause is that, unlike previous attempts to create a unified approval procedure for new medicines, the authorisations issued by the EMEA, once endorsed by the Commission, are binding and valid throughout the EU. Obviously, the purpose of single authorisation process is to avoid the duplication of effort by fifteen different national regulatory procedures, a review process that is considerably more specialised and expensive than for traditional industrial products (including medical devices), thereby easing bureaucratic and administrative pressures on manufacturers and national administrations alike. It also speeds the time required to bring new products to market; again a process that is unique to pharmaceuticals in terms of the time and detail required. However, an EU-wide system also has the effect of removing a great deal of responsibility from the Member States.

As far as the authorisation process itself is concerned, on the basis of work carried out by national authorities acting as rapporteurs for each drug applications, the EMEA makes recommendations to the European Commission which then delivers the decision. The national agencies thus have little say over what drugs are being approved for their market; the EMEA procedure simply makes use of the existing Member State machinery. The Member States are entitled to question and even reject an authorisation issued by the EMEA, though such disputes rarely occur. In the even that they do, they are referred back the agency via its Committee for Proprietary Medicinal Products (CPMP) to be resolved.

As the body responsible for deciding on behalf of the EMEA, the probity of the CPMP must be ensured. Consequently, it is comprised of scientific experts from each of the Member States who are nominated by their national administrations, and these individuals are required to put aside any national or other interests they may have. By seeking to exclude vested interests, the intention is to guarantee scientific decision-making of the highest quality. Indeed, both manufacturers and Commission officials have been at pains to stress their considerable satisfaction with the agency and its work so far. Nevertheless, the EMEA has not been entirely free from criticism.

Continuing criticisms

Unhappiness with the agency relates primarily to the nature of the system and the resultant abrogation of social responsibility at national level. It has generally taken two albeit related aspects, both of which carry implications for national health care systems. The first criticism, from several analysts and commentators, has to do with a perceived lack of transparency in the agency’s work (167), which may lead to undue influence by industry. As a corollary perhaps, the second critique asks whether the agency’s work to date (and perhaps even its remit) is therefore

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1 Towards this end, the CPMP reassesses the authorisation and issues an opinion which the Commission is again expected to rule on. The Commission then delivers a final and binding decision to which the Member State in question is then required to adhere.
geared more towards the needs and interests of industry (i.e. the applicant) than it is to the consumer. Thus, it is claimed that the agency’s emphasis is on improving time-to-market (TTM) for new drugs is given precedence over protecting public health.

The first charge is one that the agency has fought since its inception, with some degree of success. Primarily through the maintenance of an updated and relatively user-friendly website (www.eudra.org), the EMEA has sought to make its activities accessible. The site posts a considerable array of information and material, ranging from the usual ‘Who we are/what we do’ and ‘Frequently-Asked Questions’ summaries, through a listing of all legislation pertinent to medicines in the Community. It also includes contact details for all staff involved in the agency’s work, including those at the national level. More importantly, it publishes the Summary of Product Characteristics (SPC) for new drugs and the detailed assessments of new applications, known as European Public Assessment Reports (EPARs), for all positive opinions granted under the centralised procedure. Although much of this material is very specialised, it confirms the agency’s self-declared open approach.

The nature of this information has, nevertheless, been questioned, and the charge of secrecy has not gone away. It is one that reverberates especially sharply with those interested in the public health dimension of medicines regulation in the Community; particularly as the ‘public health test’ is now a supranational rather than Member State responsibility. Thus, the International Society of Drug Bulletins (ISDB) has argued that the information on the EMEA website is opaque, inconsistent, and unhelpful. It has characterised the EPARs as “increasingly hazy and irrelevant.” It accuses the agency of employing obscure and coded language in the presentation of these reports that diminishes the value of their content (168). Consequently, the ISDB has long sought improved access to EMEA information. While issues of commercial and industrial secrecy must be respected, exclusion of the general public from even basic information does not inspire confidence where public health is concerned.

SPCs have also been criticised. These are supposed to provide detail about individual drugs in order that interested parties, primarily physicians and national regulatory officials, can obtain objective information about the drugs, thereby allowing them to better understand how they work. First, unlike many national agencies that distribute their findings to physicians, physicians must look for information from the EMEA themselves. It has thus been suggested that national regulatory agencies should be able to distribute SPCs (169). Next, the SPCs describe drugs without reference to similar preparations, let alone those designed to treat similar conditions. Furthermore, the manufacturers are themselves involved in writing both SPCs and the EPARs, leading to some variation in the quality of these documents (168). This prevails despite a process of harmonisation of summaries under a centralised process; the majority of medicines circulating in Europe do, however, predate this process, and thus carry often widely differing summaries.

Such continuing failings have led to the second line of criticism; namely, wider questions about the agency’s true function. While established to regulate the safety, quality and efficacy of new medicines in Europe, the EMEA is widely viewed as serving primarily the interests of industry. Both the agency and the Commission (and the industry) have consistently stressed public health as the EMEA’s first priority but many commentators remain unconvinced. They ask why, for instance, the applicant companies are privy to the CPMP’s consultation documentation (that includes preliminary votes by the committee’s Members) prior to the final decision (169). This gives manufacturers an initial ‘feel’ with regard to how the authorisation is going, and allows them to either withdraw the product before assessment or else accept a preliminary negative decision at an early stage in order to have time to prepare an appeal.
In addition, details of negative decisions or those in progress before a company's withdrawal of the proposed product are not published on the agency's website alongside positive decisions. A comparison between 'acceptable' and 'not acceptable' judgements would offer interested parties, particularly doctors and national regulators, the chance to see the EMEA's criteria in practice. Instead, only the industry is privy to this comparative information. Withholding such information does not seem to serve patient interests. In fairness, however, prior to 1995, when there was neither a centralised European agency nor a website, information about the review process and applications under consideration, such as EPARs or SPCs, was even less available than now.

A further concern is that the industry is able to choose one of the two CPMP officials that acts a rapporteur in the application. This does not imply that public health is compromised - clearly, more lax EU standards than those applied by Member States could not be countenanced by European or national policy-makers - but it is to question the industry's role in the EMEA's work and to ask about the lack of transparency as perceived by many analysts.

**Reviewing the MDD: the prospect of a European agency for medical devices?**

As previously noted, there is no equivalent to the EMEA for medical devices. This is despite forceful arguments during the late 1990s by the French government for a European regulatory office. Unlike medicines, there was insufficient support from Member States. More importantly, the industry was not interested. The idea has, however, recently resurfaced in the context of changes to the EU regulatory environment for devices. With the continuing globalisation of the sector, and the implementation of a system of Mutual Recognition Agreements (MRA) with the United States, there have been calls to re-assess the current framework. A discussion of the Mutual Recognition Agreements between the EU and the United States is beyond the scope of this paper, though it should be mentioned that their general purpose is to improve each party's access to the others markets. Specifically, the French and British governments have asked for a review of the Medical Devices Directive, and this has rekindled the idea of a centralised European office. They seem to feel that the current system represents a lowest common denominator rather than a functioning Europe-wide regime, and they are seeking to retain their own stricter national requirements.

The UK's call for a review of the MDD was put to the European Commission by the UK Medical Devices Agency (MDA) at the end of 2000. The MDA's position was that:

Overall, we believe that the MDD has worked reasonably well since its introduction in 1994, but several factors led us to call for this review. These included the adequacy of safety controls in some areas, rapid changes in the device industry and the technology which underpins its, and the proposed enlargement of the European Union.

Concerns about particular groups of devices and some system-wide concerns were also cited as problem areas. These were said to require either improved 'guidance' from the EU or else major amendments to the current legislation. One of the problems identified, as with the EMEA, was a question about the transparency of the framework; though more with regard to clarifying the device manufacturer's position, rather than commenting on the process itself. Another concern was the need for improved clarity as to who bears responsibility for placing medical devices on the market. The Commission has taken the UK's submissions into consideration, along with those of other Member States, and is expected to deliver its conclusions soon.
Pricing and reimbursement issues

The Community has no specific competence with regard to the pricing and reimbursement of medicines and medical devices under national health care systems. Pricing controls are the responsibility of Member States. The mechanism employed may reflect a variety of factors and usually requires a balance between affordability and a reasonable reward for innovation. Thus, the UK operates a system of profit controls on manufacturers (the Pharmaceutical Price Regulation Scheme, PPRS), while in Germany prices reflect the availability of alternative products. This involves either generic substitution or 'reference-pricing' in relation to the lowest-priced equivalent. Decisions are made by the Bundesausschuss der Ärzte und Krankenkassen (BÄK), the Federal Standing Committee of Physicians and Sickness Funds, allowing the Sickness Funds to make considerable cost savings (172).

Recently, however, this system has been challenged under both German constitutional law and European competition law (173). The question is whether the German reference price system, given the BÄK’s role, infringes European competition law. In 1999 a German court ruled that the Sickness Funds’ price-setting responsibility represented a violation of the EU’s regulation of cartel practices, and on 03 July 2001 the German Federal Supreme Court decided to refer this to the European Court of Justice for a preliminary ruling (see also chapter 3).

Importing and reimbursing medicines: the Duphar ruling

Although the Community does not have a role in the pricing of drugs per se, it does have an indirect effect. For instance, in 1984 the ECJ delivered a ruling in the Duphar case (174) which enabled Member States to organise their health social security systems in a way that sustained financial stability. The case involved Dutch law, which excluded certain drugs from the compulsory health care scheme on the basis that there were other medicines with the same therapeutic effect available, but which were less expensive. Although seemingly running against the free movement of goods provisions of Article 28, the Court in fact ruled that such restrictions were permissible, but only if they promoted the financial security of the health insurance schemes. While not representing a formal restriction on the free movement of medicines in the Community, the ruling did provide for a potential indirect restriction on imports, depending on how the decision was applied. Thus, for the legislation to be consistent with Article 28, the Court stressed that the choice of medicines excluded from reimbursement must meet certain objective criteria. Furthermore, these criteria had to apply regardless of the origin of the medicines. Where this criterion was fulfilled, any medicine could be imported into The Netherlands (and thus any Member State) providing that it had the same therapeutic effect at lower cost than products already available.

Another by-product of the ruling was that national controls on doctors’ prescribing behaviour, in terms of only certain products being reimbursable under social security systems, was deemed consistent with the Treaty of Rome. The legal basis for the national implementation of so-called ‘negative’ and ‘positive’ lists was endorsed by the ECJ ruling. Since then the Duphar case has been widely invoked to underline the case that Community law does not detract from the powers of the Member States to organise their social security systems.

Similarly, the European Commission recently decided to pursue infringement proceedings against Greece for introducing national practices with regard to the reimbursement of medical devices, which, it was argued, violated free movement principles. The Commission issued a formal request ('reasoned opinion') to the Greek government to alter its reimbursement rules as they discriminated against products imported from other Member States. Specifically, a 1999 government document stated that, in order to qualify for reimbursement, certain orthopaedic
devices were required to carry the ‘serial number’ of the insured. Furthermore, the product invoice was to refer to the professional licence of a special technician for such products. Not only was this viewed as a potential limitation on imports, but as the document also stipulated that imported products that were more expensive that Greek ones would not be reimbursed, the Commission took the view that this was clearly against Article 28.

The ‘Transparency Directive’

The initial push for a ‘European’ dimension to pricing methodologies, not in terms of a standardising prices, but with regard to making pricing policies objective and clear, came with Directive 89/105/EEC. The so-called ‘Transparency Directive’, which came into force in early 1990, was designed to assure open and verifiable criteria in national pricing and reimbursement decisions. This was to ensure that national policies did not inhibit the trade in medicines in the Community; in other words, to ensure the functioning of the single market. The final Directive was a thinner version of the first draft issued by the Council in 1986, in which the Commission had proposed measures that would have promoted price harmonisation. As this was not realistic in light of Member States’ opposition, the Directive’s preamble refers simply to “further progress towards convergence”, and the Commission acknowledged that it was only an initial move in a step-by-step approach towards eventual price harmonisation (175).

The Commission did seek to launch a second Transparency Directive, but this failed as the other stakeholders were unwilling to address the issue in the terms the Commission wanted. First, the industry voiced its concerns about direct Commission involvement in Member State pricing policies as potentially harmful to business. And the Member States, at least those who responded to a Commission questionnaire in 1992 as a follow-up to the original Transparency Directive, generally emphasised that they would not accept any Community infringement on their sovereignty where health was concerned. The then Commission Vice-President, Leon Brittan, attributed this to Member States exercising the principle of subsidiarity, which he saw as representing a formal limitation on the further development of Community competence in the area of pricing (176). The price differentials that the Commission sought to overcome in the Transparency Directive discussions, and which continue today, have led to the practice of parallel trade in medicines in Europe since the 1970s.

Parallel Trade I: the realities of price differentials

Parallel trade is one of the most vexing issues concerning pharmaceuticals in the single market. It involves the purchase of branded medicines in one Member State, and their sale at below the market price pertaining in another, more expensive Member State. Specifically, this entails a distributor buying drugs from wholesalers in cheaper countries and then exporting them to more expensive countries where they are then sold on to local wholesalers (often directly to pharmacies as well) at prices lower than the manufacturer is itself offering them in that market.

As this has considerable cost-saving implications for national health care systems, it is not surprising that several Member States have effectively endorsed it as a means of reducing health care spending. In the UK alone the number of prescriptions filled by parallel imported products rose from one in ten in 1997 to one in eight by 1998, and, in 1997, applications to the Medicines Control Agency (MCA) for parallel licence imports increased by 18% compared with the previous year (177). It should be noted that the MCA grants a product licence to import a drug only after it has been shown that it is therapeutically equivalent to the domestic version. Nonetheless, as this parallel importation impinges on the profit-making abilities of the manufacturers whose medicines are being ‘parallel traded’, they tend to oppose the practice.
The main reason for the development of parallel trade in prescription medicines is that considerable price differentials exist amongst the Member States. In the UK, for example, the retail price for an identical product often exceeds that in France or Spain by up to 100% (178). Because medicine pricing and reimbursement is tied to national health and social security systems, and are thus subject to the jurisdiction of Member States, such differentials are permissible within the single market. This is not the case for other commodities such as automobiles where the European Commission has taken steps to harmonise national pricing regimes. As these price differentials for medicines cannot be ‘legislated out’, parallel trade has developed as an acceptable manner of ensuring relatively equal access to the same drugs throughout the Community, whilst at the same time fulfilling the free movement requirements of the SEM. This has been the view of the ECJ in several important cases so far.

Another reason for the consolidation of this practice, although more difficult to substantiate, is that parallel trade can help check what many view as excessive industry profits. As industry is often accused of actively exploiting the differences between national regulatory systems, hence its reluctance to endorse a true single market in medicines, parallel trade evens the playing-field somewhat. Both factors have unquestionably had a role to play in fostering the practice and, according to Hancher:

It is probably fair to say that the truth of the matter lies somewhere in between these two poles: the industry must continue to live with a scattergram of national policies on pricing and profit control, but is of course able to react to this situation in a number of ways, even it cannot necessarily control it. Price divergences have been further fuelled by currency movements. (179)

It seems, therefore, that there are both benefits and disadvantages to the practice. Concerning the disadvantages, the industry claims that parallel trade gives an unfair competitive advantage to distributors and thereby undermines their ability to undertake costly research and development; or that lower profits mean less innovation. The result, in practice, is that companies may, potentially, withdraw products from the market on non-health-related grounds: something that they are not permitted to do. This has lead to bitter complaints from several groups, most notably the European Generics Association (EGA), that by such withdrawals the large manufacturers compromise public health (180).

Turning to the benefits, it is clear that parallel trade does promote competition. This is important not just because it fosters research and development, but also because large companies enjoy many of the advantages of effective monopoly power (181). More players could potentially lead to greater choice for the purchaser. The wider availability of lower-priced, though still innovative and efficacious medicines, might also, eventually, bring about some degree of price convergence. Thus, the European Commission has traditionally seen removal of price differentials as central to completing the single market (182). Ultimately, parallel trade could help bring about closer market integration; something that the ECJ has recognised in several rulings it has delivered in favour of the practice.

It should, however, be recognised that the empirical evidence on the effects of parallel trade (both good and bad) is limited. Based on data from Sweden, the authors of a recent study have concluded that: “... the prices of drugs subject to competition from parallel imports increased less than other drugs during the period 1995-1998. Approximately ¼ of this effect can be attributed to lower prices for parallel imports and ¼ to lower prices charged by the manufacturing firm.” (183) This would seem to bring benefits in terms of health spending. However, the authors go on to say that “Econometric analysis finds that rents to parallel importers (or resource costs in parallel trade) could be more than the gain to consumers from lower prices.” There are,
therefore, mitigating factors. While the jury is still out concerning the long-term impact of parallel trade, manufacturers have nonetheless tried to limit the practice where possible. For the most part they have attempted to do so through European courts on the basis of intellectual property infringement, an issue explored later.

**Questions of free movement**

The 1957 Treaty of Rome established the earliest rules regarding the free movement of goods. It also laid down provisions on competition, a field in which the ECJ has been extensively involved. Both sets of provision affect the movement of medicines and medical devices in the Community.

European competition law there is an immediate tension, stemming from its dual role. In addition to fulfilling the classical requirement of ensuring the lowest (fair) price for goods and services, along with the best allocation of resources, European competition law is designed to promote, or at least facilitate, the single market. It seeks to ensure that private enterprise does not treat the fifteen different Member States as independent markets. Accordingly, European competition law is enforced not just at the supranational level, but equally in the Member States through its integration into national legislation. This dual function, and the tension which results, has accorded the ECJ a prominent role where competition issues are concerned, and particularly so over matters of intellectual property.

**Intellectual Property**

Intellectual property rights are central to all high technology industries, such as pharmaceuticals and medical devices given the investment required in new products. The need to recover massive research and development costs (both in time and financial terms) and to remain competitive in a tight global marketplace has driven many drug manufacturers to seek extensive European-level intellectual property rights. They have done so primarily through direct action; either by unilaterally lobbying their home governments on the need to recoup costs or, jointly, through, their EU trade organisation, the European Federation of Pharmaceutical Industry Associations (EFPIA), lobbying the Commission on patent durations. Another approach has been to bring a variety of cases before the ECJ to seek clarification, most notably on intellectual property issues.

The pharmaceutical industry’s lobbying on intellectual property rights has been quite successful (184). During the 1980s its pressure on national governments resulted in some countries - France, Italy and the United Kingdom - either establishing, or seeking to do so, extended patent protection periods for medicinal products. The desire of these governments to both ensure the profitability (and hence the economic contribution) of local industry and the procurement of efficacious medicines, saw them side with industry and, unilaterally, invoke national derogations from the standard provisions of the European Patent Convention. Such pressure at the national level inevitably emerged in the European arena and, given mounting pressure from EFPIA, ultimately required European Commission action. Following much political negotiation, this took the form of Regulation 1786/92, otherwise known as the Supplementary Protection Certificate.

**Extending patent times for medicines: the Supplementary Protection Certificate**

Notwithstanding the fact that, as with other industrial products, pharmaceuticals fall under the auspices of the 1973 European Patent Convention (EPC), in 1992 the Commission introduced the Supplementary Protection Certificate (SPC) legislation in order to extend patent protection times. Manufacturers were granted 15 years protection for their products from the date of first market authorisation in the Community; the EPC provided 20 years from first patent application. The
passing of the new Regulation was not an easy affair as the Commission was subject to intense lobbying by the major stakeholders. Several drafts were thus prepared over a two-year period before the final text was adopted.

The reasons for this lengthy process stem from the, at times, vastly different interests of the stakeholders. The research-based industry argued that, as the number of new chemical entities (NCEs) being discovered was diminishing, the length of the discovery and approval processes (and hence their own costs) were increasing (185). Lengthier patent protection would allow them to recoup their costs and reinvest them in research and development. The European generics industry was not in favour of more protection as longer patent times lessened their ability to compete, at the same time as their own research and development costs were rising. Consumer and patient groups also opposed the legislation, arguing that it represented a setback to the patient who would not only have to wait longer for (generic) medicines, but would also and have less choice.

The Member States also expressed concerns with the SPC proposals. Their primary interest was in controlling health care costs and it was felt that patent extensions could delay the introduction of cheaper generics, thereby keeping drug prices high. Generic substitution was developing as a popular cost-saving mechanism in several countries. (186) There were, however, differences within this broad position. Countries such as the United Kingdom and Germany, which have major research-based industries, were initially reluctant to see patent times extended because of the effects any changes might have on pharmaceutical prices. Others Members such as Greece and Spain, with generic industries, simply opposed the proposals outright.

Parallel Trade II: what role for intellectual property rights?

The reasons for the development of a parallel trade market in medicines in the Community were outlined above. So too was the industry's displeasure with the practice, with the consequence that the ECJ has played an important role. In the subsequent section we look at how manufacturers have sought to limit parallel trade, and what the ECJ's role has been.

The industry's unhappiness has been manifest by some of the large research-based firms taking parallel importers to the European courts on several occasions, on the formal grounds that parallel importation represents an infringement of their copyright and trademark rights. Informally, industry representatives also claim that the practice undermines innovation by undercutting the amount of money they can put into the research and development process for new drugs, as well as reducing their (and hence Europe's) competitiveness in the global marketplace. The implications of this position are that: (i) companies benefit from the current divergence in national prices and comparative lack of competition in the market; and (ii) that profit drives innovation. Neither can be adequately sustained. Nevertheless, as the costs of bringing a new drug to market have risen over the past few years - some industry estimates are now as high as €500 million185 - there has been a growing tension between the major stakeholders over the practice of parallel trade in medicines, bringing the ECJ into play. It should however, be noted that such cost data are supplied by the industry and include many factors that do not apply specifically to the generation of any single product. It is therefore advisable to treat these estimates with a degree of caution.

In its many rulings in this area, the ECJ has had to address several issues. First is the extent to which the practice is in keeping with internal market priorities. Second is the issue of intellectual property rights and the doctrine of European and international exhaustion of rights. Exhaustion of rights applies where a company chooses to market a product in two or more Member States. In doing so, it takes advantage of opportunities for international trade, and so exhausts its rights to
control subsequent trade in the product in question by others between the States concerned. This raises wider issues relating to competition, particularly as manufacturers have been accused of trying to limit wholesalers’ ability to sell to parallel distributors. The final question is how to ensure public health. Commentators have often sought to underline the value of parallel trade in enabling national health care systems to afford the (high quality) branded medicines and so benefit public health. A brief summary of several of the Court’s more important rulings shows how one or more of these often over-lapping issues have been addressed.

**The ECJ and aspects of parallel trade case law**

As mentioned previously, European law according to Article 28 (ex 30), prohibits restrictions on imports or other measures ‘having equivalent effect’. But Article 30 (ex 36) does permit certain derogations, including where the protection of industrial and commercial property is concerned. This derogation is permitted insofar as it does not constitute a ‘means of arbitrary discrimination or restriction on trade between Member States.’ This exception has been invoked by pharmaceutical companies on several occasions as a means of limiting parallel trade although their attempts have been unsuccessful. The ECJ has generally ruled that once a medicine is made available in any two national markets with the manufacturer’s consent, the manufacturer cannot then employ the intellectual property derogation of Article 30 to prevent any subsequent trade of the product between the two countries. For this reason, ECJ rulings have addressed copyrights, trademarks and patents (179).

The Court’s decisions have often centred on the ‘exhaustion of rights’ principle. For instance, in 1974 the ECJ ruled that, once a company sells its product in a second market, it has recovered its so-called ‘motivation reward’ and cannot then seek to influence any further Community distribution of that product (187). The Court held that allowing the patent holder to restrict distribution – as a means of preventing parallel imports – was tantamount to sanctioning the continued partition of national markets, thus violating Article 28 (ex 30). This interpretation of the exhaustion of rights doctrine has been re-affirmed and widened in subsequent cases.

In the *Stephar* case brought by Merck & Co. Inc. (hereafter, Merck) in 1981 to prevent the parallel trade of its anti-hypertensive drug, *Moduretic*, between Italy and the Netherlands, the ECJ went even further (188). It did not simply uphold the principle that the patent owner’s rights were ‘exhausted’ once sale of the relevant product had occurred with their consent, but held that this applied even where there were differing intellectual property rights between the countries involved. In this case Merck had patents for the drug in all Member States except Italy and Luxembourg, and for its manufacturing process in all the Member States except Denmark, the Federal Republic of Germany, Italy, and Luxembourg. The Court ruled that arbitrage between the Netherlands and Italy could not be hindered even if patents were not held in the country where this sale took place (Italy). The ‘exhaustion of rights’ doctrine applied even when the second Member State did not provide patent protection; even if this meant reducing the return on investment of patent holder The argument was that, by releasing the product in a country where national law does not provide intellectual property protection, companies must accept the consequences of further distribution within the EU and that withholding sales to avoid exhaustion could be left to the patent owner’s discretion. This ruling set a precedent in reversing an earlier decision that there was no such exhaustion of rights if there was no patent in the country of first sale (189).

More recently, in 1996, the Court delivered its judgement in the *Primecrown* joint cases, which had also been brought by Merck (190). Here the issue was the parallel importation of certain medicines from Spain and Portugal that were, prior to each countries’ accession to the Community in 1986, not patented in either. Merck’s concern was that, with accession, the effect
of existing EU case law on intellectual property rights exhaustion would have permitted generic products from Spain and Portugal to be exported to other Member States where the products were protected. The Court permitted the patent owners to continue using their patents for a ‘limited period’ to prevent importation from Spain and Portugal. However, questions arose with regard to the duration of this ‘limited period’, and whether law on parallel importing should in fact be up-dated in its entirety.

Merck argued for a complete review of existing law, given both the increase in parallel importing since the Stephar ruling, and because the Supplementary Protection Certificate, which had in part been designed to overcome this, would lose its meaning if parallel imports from the Iberian countries were to be permitted. It was argued that the research and development context had changed, as had the price differential between Spain and Portugal and the rest of the EU since the Stephar ruling. Merck claimed that pharmaceutical manufacturers generally have no choice other than to market their products, and that the idea of exhaustion at the time of sale should not therefore apply; how could they exhaust patent rights they did not in fact have? The Advocate General’s recommendation was that the patent holders should be able to prevent parallel imports from Spain and Portugal and that Article 28 (ex 30) should not disadvantage the patentees when they did not previously enjoy patent protection in a country from which products are later exported. Nevertheless, despite the Advocate-General’s recommendation, the Court maintained its view on exhaustion line in previous rulings. These cases have since been the subject of extensive analysis and it has become clear that intellectual property rights are not a barrier to parallel trade in medicines within the Community. Nevertheless, there are potential problems because intellectual property rights continue to differ among countries.

**The Bayer ruling: a new approach to prevent parallel trade?**

The most recent case concerning parallel trade and the pharmaceutical industry was the appeal (05 February 2001) to the European Court of Justice by the European Commission against the Court of First Instance’s decision of 26 October 2000 to quash a €3 million fine levied on the German drugs company Bayer (191). The fine had been awarded by the Commission on 10 January 1996 for what was viewed as uncompetitive practices by the company. Specifically, Bayer was said to have attempted to prevent the parallel trade of its cardiovascular drug, Adalat to the UK market from France. At the time, Adalat was available for approximately half the UK price in France (192). Given the rulings discussed above, Bayer had not sought to exercise intellectual property rights to reduce trade. Bayer was instead accused of limiting deliveries of the drug to wholesalers in France and Spain (as supplier countries to the UK). Through collusion with its own wholesalers in those countries, Bayer was accused of trying to prevent the drug being sold to distributors who might re-sell it to the UK.

The Commission’s case was based on Article 81(1), which prohibits agreements between companies that amount to restrictions on competition (cartel practices). Bayer claimed that it had acted unilaterally and not in collusion with its wholesalers, and launched an appeal which was upheld by the Court of First Instance in 1999. The Court did not find sufficient evidence of the Commission’s claim of bilateral collaboration between Bayer and its wholesalers, and supported Bayer’s argument that it had not imposed what the Commission had claimed in essence amounted to an export ban. The Court’s decision was based on its finding that Bayer had no ability to control subsequent distribution of its products (that is, beyond distributing to its wholesalers). Furthermore, the company had no policy to ensure that the wholesalers did not export, nor one to sanction those that did. The Court thus quashed the fine and ordered the Commission to pay Bayer’s costs.
In appealing this reversal to the European Court of Justice, the Commission has stressed that the ruling does not call into question the principle by which obstacles to parallel imports or exports are banned. Put quite simply, the Commission “wants to continue its policy under Article 81(1) of challenging agreements between a manufacturer and his distributors, e.g. supply quota arrangements, which partition the common market along national lines.” (193) This was a sentiment also expressed in the Commission’s earlier decision of 08 May 2001 to prohibit Glaxo Wellcome from operating a dual-pricing scheme (194). Glaxo Wellcome was charging its Spanish wholesalers higher prices for those medicines it was planning to export, than those intended for the domestic market. Although neither the Bayer nor Glaxo Wellcome decisions are intellectual property cases per se, they are further indication of the drug companies’ displeasure with the practice and their various attempts to limit it; not to mention the Commission’s ongoing push for a single medicines market.

The future of parallel trade?

Beyond taking the parallel importers to court, the industry has other tactics that it employs to limit the practice. As well as claiming that the safety and quality of the parallel imported products can be undermined in attempts to repackage the drugs, these include:

... making products available only in small batch sizes; supplying direct to pharmacy outlets at reduced prices; applying for licences in different strengths of drug dosage (for example, 10mg strength in Spain but 20mg in Germany)...
different pack sizes [and] making tablets of different colours, shapes or with different packaging. (195)

It remains to be seen, however, whether these tactics can be legislated against effectively, i.e. are they ‘police-able’ in the future? If not, how they can be properly regulated within the single market.

All the Court cases so far outlined contain a tension between support for intellectual property rights and promotion of the single market (and not just for medicines), which continues even today. According to a study commissioned by the European Commission in 1994:

The European Community’s policy for intellectual property is twofold: on the one hand it wants to ensure that “products” are adequately protected both internally and externally, while on the other, it seeks to harmonise national legislation on intellectual property rights so as to remove any trade restrictions between Member States. In particular, the Community seeks to establish greater protection of intellectual property rights... and efficient control over illegal and counterfeit goods. (196)

The most likely result of this tension is that parallel trade will continue for the foreseeable future. Any ECJ ruling that seeks to abolish it would, in essence, be undermining the free trade principle that lies at the heart of the single market. While the Court has toned down its apparent support for ‘integration through free movement‘, as change would also require the approval of both the Commission and the Council, any compromise on what many regard as the fundamental basis of the European Union, seems highly unlikely.

Other issues regarding free movement

As the Community consolidates the regulatory regimes for medicines and medical devices, European law is likely to continue to play a major role, which will extend to other areas. This will
require further changes to national health care systems, with implications for Member State’s decision-making power; for instance, the British government’s recent announcement on obtaining treatment abroad.

**Product/ Producer Liability**

For both medicines and medical devices, the Community is continuing to develop a Euro-regime in the field of product liability. Disparate national laws on the right of consumers to seek redress from the manufacturer for any loss or injury incurred through the use of a product have been harmonised by a 1985 Directive (Directive 85/374/EEC). These diverse national systems were seen as hampering both the free movement of products and the development of a common market for consumers. Thus, the Directive established a stringent liability protocol requiring litigants to demonstrate not simply that the product was defective, but that injury occurred as a direct result. Until then, national rules had generally required the litigant to prove that the manufacturer had been negligent and that it had therefore been aware of the problem.

There has been much recent discussion about amending the Directive and, on 28 July 1999 the Commission issued a Green Paper on Producer Liability (197). In doing so, it set out two aims: first, “to enable practical and factual information to be collected from those concerned (in particular industry and consumers), in order to assess how the Directive is applied ‘in the field’, and to establish definitively whether it is achieving its objectives”; and second “to ‘gauge’ reactions to a possible revision as regards the most sensitive points of this legislation.” EUCOMED, the EU medical device manufacturers’ umbrella organisation issued a response which, amongst other things, served to stress the differences between medical devices and other products where producer liability is potentially an issue (198). They also stressed that the current (predominantly national self-regulation) rules were more than adequate to assure safety and efficacy, and that there was little need for any substantive adjustments for medical devices.

**The Internet, electronic commerce and medicines**

Another area in which the Community will soon be required to take a stance is with regard to ‘e-commerce’ and the role of the Internet vis-à-vis medicines and medical devices. The implications of the World Wide Web as both a source of information and a vehicle for purchases has been recognised by the Commission as having specific implications for pharmaceuticals and it featured heavily in the 1996-1998 Commission ‘Roundtable’ discussions with the industry on measures towards completing the single market.

Beginning with the information issue, there are innumerable disease and health-dedicated websites. Health-related sites are not only the most numerous, but among the most frequently visited. There is an enormous amount of information ‘out there’. The complexity of the information and the challenge of judging its applicability in different circumstances means that few people have the specialised knowledge needed to interpret the information on offer. Worryingly, it also widely recognised that much of the information available on the Web is outdated, misleading, untested and often wholly incorrect. There is a further question as to who is providing the information, why, and how responsible they are. At present, many sites are sponsored by the large pharmaceutical firms, which immediately suggests a potential conflict of interest with regard to presentation of the material as it opens the door for manufacturers to promote their own medicines on these sites, an action that is contrary to the ban on direct-to-consumer advertising in Europe (see below). This poses problems for European policy-makers on several levels. While the possibility of independent regulation of these sites to ensure their accuracy and quality might seem an answer, in the short- to medium-term at least, the practical implications of implementing such a system are not immediately apparent.
As well as having instant access to reams of unregulated information, the continuing growth of the Internet in Europe, though still well behind the United States, has brought with it the possibility to buy medicines on-line. Thus, the Internet is proving a major contributor to the growing practice of mail-order trade in medicines. Given the continuing price differentials between Member States, it is clear that the EU will have to develop an explicit policy. Countries such as Germany, that have made mail order trade in medicines illegal (since 1998), are finding that distributors and pharmacists in other Member States are shipping to their markets, defending their right to do on the principle of free movement. Germany has in fact banned the sale of all prescription and OTC drugs outside of pharmacies, and pharmacists themselves have expressed reluctance to move to e-commerce even should the regulations be changed. This is not the case in all of Europe, where different Member States have different views; derived in part from varying degrees of Internet penetration.

In the UK e-commerce is generally held in a positive light; no doubt due in part to similar business practices (not to mention a common language) with the United States. In 2000 the British government issued a White Paper entitled 'A New Future for Communications' which set out the government's aims to give virtually everyone access to the Internet by 2005. Thus, it is perhaps not surprising that the Royal Pharmaceutical Society supports the development of the 'e-pharmacy' and has set out guidelines for its operation. In France, meanwhile, the Internet has not yet permeated the mundane to the same degree; largely because of the prevalence of the so-called 'Minitel' service which all homes have access to. France is, however, slowly catching up, though it remains to be seen whether e-commerce will take off as it has in Sweden or Switzerland for example. In the former, all pharmacies fall under the state umbrella organisation, Apoteket – which has its own website – and which could therefore potentially act as a catalyst for medicines e-commerce. This is especially likely as Sweden is one of the most 'wired' countries in the EU. Switzerland, although not an EU member, has already embraced the Internet as a way to buy medicines. In 2000 some 16% of all prescription and over the counter (OTC) medicine sales in Switzerland were acquired via mail-order or online. Effective regulation at the European level must take account of this diversity.

As previously mentioned, the expansion of the Internet also has ramifications for the divisive issue of drug advertising. As a result, the European Commission is slowly starting to re-assess the European position on banning direct-to-consumer marketing in the face of a strengthening US market, which permits it.

**Pharmaceutical Advertising**

The provisions governing the advertising of medicines in the Community are another example of how European law impacts on matters affecting national health care systems. In 1992 the Community set out to harmonise Member State rules on advertising medicines for human use as part of the single market programme. Directive 92/28/EEC differentiated between advertising to health professionals (doctors and pharmacists) and that aimed at the general public. The former pertains to prescription medicines (and those containing narcotics or psychotropic substances), and the latter to OTC preparations. Advertising for non-prescribed pharmaceuticals is first subject to the need for market authorisation of the relevant product.

National advertising rules differ substantially between the Member States. For instance, while Belgium and Denmark have traditionally banned the advertising of OTC medicines on all audio-visual media, Sweden, Italy and France have insisted on pre-notification for OTC advertising. Belgium and France meanwhile, have outlawed all sales promotions for OTC. Even among those countries that do have similar advertising regulations, the specific requirements can
also be quite different. For example, with regard to television advertising, some countries require that very stringent warning messages accompany the advertisement, or that the advertisement be only of a particular length. Another problem for advertisers has been that the same products are not available in all Member States, either in terms of those on positive lists or reimbursed via national social security systems.

In laying down the Community rules, the pharmaceutical advertising Directive has tried to overcome these differentials. Key amongst its provisions is a reference to an earlier piece of legislation, Directive 84/450/EEC of 1984 on advertising in general. This prohibits ‘misleading advertising’ which, where drugs are concerned, takes on an added significance. Accordingly, pharmaceutical advertising must not simply meet the criteria of the Summary of Product Characteristics, but it must also be undertaken such that recognition of the product as a medicine, and the advertising medium itself as a form of market promotion, is easy and immediate. There are minimum information requirements that product leaflets must contain, including the name of the medicine, potential side-effects, and instructions for correct use and application. Where the general public is concerned, product advertising must make it clear that taking the medicine does not guarantee the effects it is designed to offer. Where health professionals are targeted, the Directive forbids advertising that involves inducing doctors to prescribe specific products i.e. companies are prohibited from offering gifts or other inducements. The Directive also permits Member States to disallow advertising outright, though only of prescription medicines eligible for reimbursement under the national health care system.

As mentioned previously, the pharmaceutical advertising Directive was adopted to foster the free movement of products within Europe. To facilitate this, so that at least all Member States would apply similar conditions, harmonised advertising standards were deemed essential. This need is becoming even clearer as the Internet continues to change not simply the way people shop and the (unregulated) information they have access to, but also the nature of health care and its provision. The Commission has long recognised the issues arising from electronic commerce and online advertising of medicinal products. On 21 March 2000 the Commission hosted a meeting dedicated to this specific question with several interested parties; though it remains unclear on what basis those attending were invited. What has resulted is a shift in the Commission’s thinking with regard to pharmaceutical advertising in general, and direct-to-consumer advertising (DTC) more specifically.

**Direct-to-Consumer Advertising: a growing debate in Europe**

DTC for medicines has long been permissible in the United States where it is viewed as cost-effective given that medical costs are covered by private rather than state-funded health insurance (202). DTC advertising spending in the US is growing rapidly, having reached US$1.53 billion for the twelve months through March 1999 (203). This growth is in large part due to the Internet, and the advertising generally takes the form of companies setting up websites to explain the relevance of their medicines as well as providing detailed information on the specific diseases they are designed to treat. In addition, the companies are increasingly sponsoring a variety of other health care and disease-oriented websites to get their product messages across. Such activities are illegal in Europe and opposition to the idea remains widespread. The reasons for this are several fold, and are voiced not simply by patient and consumer groups, but more importantly, by doctors, medical associations and regulatory authorities.

The reasons for such opposition stem from uncertainty about any benefits DTC might bring, while there are numerous studies indicating its many problems. The industry points to advantages in ‘empowering the consumer through information’, resulting in a higher degree of autonomy and an ability to assist the doctor; as well as speedier access to medicines. This is to be weighed against
the often dubious nature of the information provided on the Web, as mentioned earlier. There is no guarantee that industry websites are necessarily better at providing higher-quality information. This is apparent from evidence that, in the United States, even over-the-counter advertisements— which are regulated by the FDA—often make inaccurate statements and neglect to mention potential side-effects (204). The dividing-line between information and advertising is therefore tenuous.

More worrisome still are other concerns about the impact of DTC advertising. Evidence from the United States (and to some degree New Zealand) would seem to suggest that it actually manufactures, rather than simply reflects, consumer need. In the words of Hoffman and Wilkes: “Extending the scope of already ubiquitous promotions about ‘post-nasal drip’, ‘unsightly rashes’ or ‘cures’ for baldness has little to do with educating the patients or relieving suffering.” (205) DTC has thus been seen as an industry tool, not for the promotion of information as they argue, but rather to make further profit. In providing information in this way, especially through the Internet, the industry can link the ability to buy on-line or via mail-order; as mentioned earlier. This eliminates pharmacists and even doctors as the ‘middlemen’, and potentially leads to the consumer relying more on medication than on advice from health professionals. In turn, this raises the prospect of more inappropriate use of medicines.

It is therefore not surprising that doctors have been amongst the most vociferous opponents to DTC advertising, and still are in the United States. Many claim that their ability to practice evidence-based medicine is being undermined (206). In addition, doctors have expressed their frustration with growing numbers of patients who come to them with demands for specific medicines or courses of treatment, based on industry promotions, and promising to go elsewhere should the doctor be unwilling to prescribe them. A survey carried out in 1999 among primary care doctors in Ohio and Pennsylvania found that most felt under pressure to prescribe drugs so marketed; and that between 30-36% admitted giving in to this pressure (207). The results of an earlier study carried out in 1997 by the Northwestern Medical School in Chicago found that physicians across America expressed generally negative views about DTC: 80% felt that it was not a good idea and 84% were unhappy with current television and radio advertising (208).

There are other fears associated with DTC. Companies may shift their advertising budgets further towards to new drugs. These are generally more expensive than existing medicines or generics, and do not necessarily bring an improved health benefit. There are other cost implications. DTC advertising in the US has been linked with both rising numbers of prescriptions issued and choice of more costly medicines, putting pressure on health insurers (209). These are all issues that any future liberalisation of the DTC rules in Europe will have to accommodate. Nevertheless, despite such evidence, the prevailing view on DTC is changing as European companies complain about their inability to compete effectively with American firms.

In the UK for instance, despite disagreeing about allowing DTC advertising, a joint government-industry Task Force (established in March 2000) agreed on the need for companies to be able to provide more information about medicines (210). This reflects the danger, as acknowledged by Enterprise Commissioner Erkki Liikanen, that European consumers are accessing a great deal of information from American company websites (211). The implication is that if European patients are going to get their information from somewhere, it might as well be from Europe. The industry’s view is that the continuing prohibition of DTC in Europe is therefore unsustainable, and legislation needs to be changed in order that accurate information can be made available to the public. This type of pressure, exerted by powerful national stakeholders such as the Association of British Pharmaceutical Industries (ABPI), is something which the national governments, and in turn the European Commission, will not be able to ignore indefinitely. Changes to the legal environment thus appear almost inevitable if Europe is to keep pace with the US.
Some national medical organisations, such as the British Medical Association (BMA) seem to have already accepted the inevitability of change. At a 20 July meeting between the BMA and the ABPI, Dr George Rae, Chairman of the Prescribing Subcommittee of the BMA's General Practice Committee, said: “We believe that what is happening in the United States now could be happening in Europe within the next five to 10 years. We want to shape what happens rather than just oppose it.” (212) In stressing specific requirements, this is a sentiment echoed by the Association of the European Self-Medication Industry (AEGSP):

Consumer-friendly information through leaflets and labels as well as the possibility to advertise in all media are important to make the public aware of a newly introduced OTC medicine. In this context, it should be kept in mind that the successful self-control instruments introduced in many countries around the globe are also competent for the clearing of switched products. We remain convinced that the best way to inform the public through OTC advertising is to mention only the name of the product, the indication and an express invitation to read the label or the leaflet (213).

Despite re-iterating that the benefits of DTC are not (yet) accepted in the EU, the European Commission has nevertheless indicated its willingness to pursue some deregulation of advertising.

As part of its review of community pharmaceutical legislation, a five-year pilot programme has been proposed by the Commission for specific disease areas - AIDS, diabetes and asthma - whereby pharmaceutical companies could make available drug information on request from a patient or consumer group. Termied disease-awareness campaigns, the companies will be permitted to provide information about their medicines either via the Internet or in specialised publications. A code of conduct on the type, content and presentation of information is still to be drawn up, and it is expected that the EMEA will asked to review this. As an aside, the choice of AIDS, diabetes and asthma for the trial still requires some clarification. While Commissioner Liikanen said that: “These diseases are long-term and chronic, there is strong patient demand for information, and the results of the 5-year pilot should be relatively easy to monitor. This will be coupled with strict control measures”, on that basis a case could equally be made for cancer or even multiple sclerosis awareness campaigns. The Commission has yet to offer any real justification for its choice. In any event, the idea has also met with criticism from several consumer groups who equate it as an endorsement of DTC, and the negative effects this can bring (as outlined earlier), and who thus fear the effects on state health care funding.

For example, Health Action International (HAI), a non-governmental organisation dedicated to 'working for a more rational use of medicinal drugs' was amongst the first to respond to the Commission’s announcement: “HAI Europe deeply regrets the recent decision by the European Commission to recommend that pharmaceutical companies be allowed to mount disease awareness campaigns. This is the thin end of the wedge to open the door to Direct to Consumer Advertising.” (214) The statement cited specific examples of where DTC has had negative effects, including promotions of AIDS drugs in San Francisco which were being considered for withdrawal for having provided misleading and unrealistic imagery about what sort of lifestyles AIDS-infected individuals could enjoy. HAI thus questions the self-regulatory nature of the Commission proposal and asks what guarantees the Commission has that European firms will behave any more responsibly.

At the national level too there has been criticism, and the United Kingdom Consumer’s Association also released a ‘briefing paper’ in response to the announcement. It accepts that there is a strong consumer push for more information but it claims that the US experience with DTC has caused
considerable harm. Specifically, the paper points to the distortion of prescribing behaviour in
favour of newer, more expensive medicines; a clear relationship between advertising and a ‘huge
increase’ in the drugs bill; that much of the DTC information provided does not in fact enable
patients to make informed choices - it is often incomplete and misleading; and that advertising is
actually being used by US companies to enforce brand loyalty and increase profits (215).

Of course it remains to be seen what the Commission is actually proposing. On the one side is the
view expressed by those who favour (or fear) that the proposal is a clear indication of the
Commission’s plan to introduce DTC in the medium-term; perhaps within the next ten years. On
the other is the perception, voiced most notably by European policy-makers themselves, that this
is intended only as a trial in providing patients with more information on the drugs that are
available to treat the three specific diseases cited (216). If it offers any clarity, in announcing the
launch of the pilot scheme, Commissioner Liikanen stressed that “This is not direct-to-consumer
advertising. We are not introducing advertising for prescription drugs. I am against direct
marketing as massive advertising could place a lot of pressure on the health costs that are
covered by public authorities.” (217) While this may be the Commissioner’s own position, it
should be borne in mind that the disease awareness proposal was made within the scope of the
review of pharmaceutical legislation more generally. Other provisions included: a fast track
registration procedure for products of ‘major therapeutic interest’; reform of the EMEA mandate
to perhaps include a role in providing scientific advice to the drugs companies (i.e. with respect to
market approval); and the idea of a Europe-wide system of pre-authorisation availability for
certain medicines on grounds of so-called ‘compassionate use’.

The basis for these accompanying proposals seems quite clear. While they may, in the
Commission’s words, aim to guarantee the highest possible level of health protection for
European citizens via the safety, quality and efficacy criteria, they are undoubtedly designed to
speed the authorisation process. And while the Commissioner himself admitted as much “We
want to increase the availability of new and innovative medicines on the European market” the
review of advertising is undoubtedly part of an effort to keep pace with the US, albeit on the basis
of anecdotal evidence rather than through any detailed examination of the evidence (on either
the potential benefits or problems) associated with the practice.

The evidence cited by HAI, the UK Consumer’s Association, and the other DTC studies mentioned
earlier, all question the Commission’s real motivation. The advertising announcement appears to
have taken none of these into account. Indeed, we are unaware of any study commissioned by
the Commission either on the effects of DTC in the United States or New Zealand, or its potential
impact in Europe. The Commission’s announcement appears a first step towards the liberalisation
of pharmaceutical advertising regulations in Europe. This would, after all, be in keeping with
previous initiatives to speed the market authorisation process. It seems likely then, that the
direct-to-consumer advertising of medicines may be developed in Europe in tandem with other
measures favoured by industry; perhaps coming sooner than may have previously been
anticipated.

**Conclusion**

Pharmaceutical and medical device policy in the EU clearly have an enormous impact on the
Member States, both with regard to shaping domestic policy decision-making, and in terms of re-
adjusting the operation and structure of their health care systems. And yet the EU frameworks for
both fields remain incomplete. There are still a host of issues to be dealt with at the European
level, promising further impact at national level.
For instance, the pricing and reimbursement of pharmaceuticals conundrum has still not been solved at EU level. There is doubt as to whether it can be. But as our discussion has suggested, the Member States appear in general more willing to countenance European intervention in health care matters than previously. Not only that, but as the European industry continues to put pressure on national governments and the EU with regard to loss of competitiveness vis-à-vis their US counterparts, both of which appear to be listening to these complaints, this may offer the Commission a renewed chance to address the matter:

The recent findings that institutional and regulatory factors might serve to protect and insulate the European industry from competition as opposed to forming barriers to the further expansion of what it usually viewed as one of Europe’s most competitive sectors may well offer the Commission a new point of departure from which to tackle the vexed issue of price regulation. (218)

It remains to be seen what form the Commission's new approach might take, though one suggestion from industry is that price controls should be instituted for those medicines which are reimbursed by national social security systems (219). A common approach to the pricing of branded medicines would undoubtedly help promote the internal market, and has the added benefit of not impacting too heavily on health sovereignty. Member States would still be able to decide their positive and negative lists, and would continue to regulate prices of all other medicines, including those subsidised by the state. It also gives the research-based industry enough room to manoeuvre in terms of rewarding innovation. As an industry suggestion, it should of course be borne in mind that the underlying rationale is to enhance competitiveness and protect intellectual property, particularly in a changing European landscape with regard to the first wave of new Member States from eastern Europe. Consequently, such an intervention could be regarded as a first step, though not as the 'end of the story'.

Indeed, the accession of these countries and their effect on the existing pharmaceutical sector is playing heavily on industry minds at the moment (and indeed European policy-makers generally). Major reforms of these health systems are going to be required, and this includes their medicine and medical device sectors (220). Currently the Central and East European countries have lower intellectual property standards and comparatively poor patent coverage, and are considerable manufacturers of generics. Perhaps, therefore, it is the prospect for increased parallel importation, coupled with moves in these countries towards permitting pre-patent expiry manufacturing of branded medicines (introduction of the so-called 'Roche-Bolar' type provisions), which is contributing to the European pharmaceutical industry's apparent mood of flexibility. They seem to be actively seeking dialogue with the Commission, the Member States and even groups representing patient interests, something neither they nor the Commission have always done in the past.

We have seen, therefore, Commissioner Liikanen call together the so-called ‘High Level Group on Innovation and the Provision of Medicines’ (otherwise known as the ‘G10’) to discuss the future of the sector. It should of course be borne in mind that the industry's interest in such collaborative effort is equally to make the case for enhancing their global competitiveness (221); and the membership of the G10 again reflects this as patient interests are not prioritised. Indeed, the idea

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1 The G10 was established on 26.03.01 and joins together the Enterprise and Health and Consumer Protection Commissioners, with selected Member State health ministers, selected industry representatives (including members of the European self-medication and generic trade groups), the Association Internationale de la Mutualité (AIM) which represents health insurance and social protection bodies, and the Picker Institute – an organisation which specialises in measuring patient satisfaction. For a complete listing of the members see CEC. DN: IP/01/444, 26-03-2001. Pharmaceuticals: high level group established to look at medicines for Europe. Commission of the European Communities.
of the G10 itself was born from a report commissioned by the Commission (DG Enterprise) into the competitiveness of Europe’s pharmaceutical industry, which was published in June 2000 (222).

It is important in the present climate of health care cost-containment, especially given the Commission’s focus on promoting the competitiveness of the industry, to consider the question of generic competition and the place of the generics industry in the current system. According to Hancher, not just ‘intra-brand (parallel trade) but so too “inter-brand (generics) competition [is] considered by the European Commission, particularly the Directorate-General for Competition, as essential for the eventual realisation of a single market across the EU.”(223) That said, the Community exercises no competence in this area, as the requisite measures such as generic substitution and influencing doctors’ prescribing patterns are matters of health care policy. These remain firmly in the hands of national governments.

The problem of a lack of industrial competitiveness in the EU was recognised in the recent report commissioned by the European Commission (222). But the reasons for this lack of competitiveness, what this means in practice, and indeed the possible solutions, are very different depending whether one asks the research or generic companies. According to the research-based industries, the report cites three reasons as to why the European industry is becoming less competitive:

- US multinationals appear to be more successful than their European counterparts in producing innovative medicines...
- The US also benefits enormously from the immense creative potential of its biotech sector
- Demand has grown much faster in the US than Europe over a comparative period, both in quality and quantity. (224)

The report’s suggested solutions include: the implementation of effective intellectual property protection; governments to support basic bio-medical research; and the pursuit of market-based competition and customer choice.

The generics industry has a different perspective. According to Andrew Kay, President of the EGA, the problems identified in the report and their solutions lie not so much with the lack of appropriate enabling conditions for innovative research, but rather the lack of support received by the generics industry:

‘… the EU lacks the triggers for generic competition which exist in the USA. The EU grants longer periods of special market protection for branded pharmaceuticals, provides no encouragement for early development of generics, and has created a regulatory system which failed to ensure the registration of generic medicines quickly and efficiently… Unless competitive generic mechanisms are put in place in the EU, the pharmaceutical sector will remain over protected and under competitive’.(225)

From this perspective, it is not simply a question of decreasing competitiveness vis-à-vis the US, but rather a lack of competition in the market. The Commission will need to address this, and quickly if the research-industry’s veiled threats about moving research and development capacity to the United States are to be avoided. But the question is how? Given the lack of a health care policy role, the Commission will have to convince the member states to pursue appropriate policies. Hancher has suggested the possibility of copying the US ‘experiment’ and moving more prescription drugs into the over-the-counter market (226). With governments keen to protect local industry, this will - as with so much in the pharmaceutical industry - prove problematic and require the striking of a delicate balance between industrial and health care policy requirements.
With regard to medical devices, further adjustments to national regulatory regimes will also be required. For example, although the new Euro-system includes the post-market monitoring protocol outlined earlier, this is not to say that it is either final or flawless in practice let alone theory. The system may appear stringent and multi-layered, but a word of caution has been expressed by at least one commentator with respect to the vigilance or self-regulation aspect; Altenstetter writes that:

... one weakness remains which will make a difference for the operation of an effective vigilance system in the medical device field. It is the absence of strong traditions in market surveillance in most Member States not only in regard to healthcare products and pharmaceuticals but also in regard to consumer goods in general.... Who is responsible for the operation of a vigilance system is hardly perceived as a responsibility. (227)

This suggests national differences in both reporting and implementation. The question is how to merge these without compromising the health and safety of patients in countries with stricter provisions i.e. avoiding regulating downwards to the lowest common denominator, while meeting industrial policy goals. Such national differences will ensure that the post-marketing surveillance of medical devices in the EU proves a complicated and difficult process.

From our admittedly selective summary of the still-evolving EU regulatory regimes for pharmaceutical and medical devices, it is obvious that national health care systems are not as free from European legislation as Article 152 might suggest. First, EU policy in these fields is aimed at achieving several concurrent goals ranging from health protection and convergence of national standards, to consolidation of the internal market and promotion of successful industries. Second, through many of its recent decisions, the ECJ in particular has made it clear that the Member States are required to apply and respect European law when organising their health and social security systems. Together these two processes, growing European regulation via the ‘regulatory state’ and the development of European law, are putting pressure on the Member States’ systems. Recent manifestations of this includes the British minister of health’s announcement on cross-border care, and what appears to be the Commission’s interest in phasing in direct-to-consumer advertising of medicines under the review of pharmaceutical legislation. When the as yet ‘unknown ingredient’ of eastern enlargement is added, with all that it brings, it promises interesting times for health care (and wider social policy) at both the supranational and national levels in the European Union.
CHAPTER 6: VOLUNTARY HEALTH INSURANCE

Introduction

Although social protection systems remain primarily within the remit of Member States, this is not so for voluntary health insurance. As with medical services, which are increasingly coming within the competence of the EU, health insurance is being considered as a mainly economic activity, and so subject to the application of European law on the single market. Even where the Community regulatory framework recognises the specific nature and social importance of private health insurance, it is far from clear how far Member States can determine the method of operation of health insurers operating on their territory. This chapter outlines recent regulatory developments at the EU level and considers the way in which they affect the market for VHI.

The non life insurance directives

Governments generally intervene in the field of insurance to ensure a stable and transparent market. This mainly relates to controlling and supervising the financial stability of insurers and their solvency.

In the past there have been two main models by which insurance operations have been supervised in EU member states: material regulation and financial regulation. Material regulation is based on the premise that if insurers are sufficiently controlled in the type of business and the level of premiums they write there can be no question of insolvency. This model applies in Germany, where the supervisory body scrutinises policies before they are offered for sale, restricts price competition by enforcing compulsory tariffs and only permits insurers who have specialised in health care to operate in the field of VHI. Financial regulation, as practised in the United Kingdom, is concerned with ensuring that the insurance company remains solvent; the regulatory body's role is restricted to examining detailed financial returns on business.

Since the 1970s, however, the European level has taken over the regulatory function by creating a single market for life and non-life insurance in the EU. In so doing it has provided the necessary legal framework to ensure the development of private insurance in an integrated European market, while stimulating competition, increasing choice for consumers and protecting them against financial loss. The focus of this Community regulation has consequently moved from material to financial control. The only distinction made is that between life and non-life insurance.

It took nearly 20 years and three generations of Directives to reach the objective of liberalising the direct non-life insurance market. The first generation allowed insurance companies to establish a branch office or an agency in another Member State. By co-ordinating legal and financial conditions, an authorisation could be obtained more easily. The second generation realised the principle of free provision of services, allowing insurance companies to cover a risk located on the territory of another Member State without having to set up a branch or agency in that Member State. However, the application was limited to policyholders whose status, size or the nature of the risk to be insured did not require special protection. For these reasons, health insurance was excluded. The third non-life insurance Directive completed the economic integration process for insurance services by extending the principle of free movement of services to all risks and all policyholders.

The single market for voluntary health insurance, as a part of the non-life insurance branch, came into effect in the second half of 1994. Henceforth, private insurers were allowed to:

• establish a branch office or agency in another Member State, without the need to receive authorisation by the competent national authorities of that State;
• provide insurance services in another Member State without the need to establish a branch office or agency.

This is realised through:
• the introduction of a single licencing and financial control system with responsibility residing with the Member State where the head office is situated (home country control);
• the mutual recognition of authorisation and prudential control systems on the state of solvency, the establishment of technical provisions and coverage of those provisions by matching assets;
• the abolition of control by the risk based Member states or prior notification of policy tariffs and contractual conditions.

Implementing the internal voluntary health insurance market

Despite the fact that the third non-life insurance Directive concluded a long process that started more than 20 years earlier, its relevance to the field of voluntary health insurance is not self-evident, mainly because it has to confront a complex and diverse situation in the Member States.

The intersection between social security and voluntary health insurance

First and foremost, private health insurance in the EU works alongside public protection systems. Health insurance “forming part of a statutory system of social security” is explicitly excluded from the scope of the insurance directives (art. 2(1)(d) Directive 73/239/EEC). Since different definitions of social security exist, there is room for confusion.

From the case-law of the European Court of Justice, it can be inferred that compulsory affiliation is a decisive criterion for defining non-economic, solidarity-based activities performed by social security bodies. Referring to the Poucet-Pistre rulings (232), the ECJ recalled in Garcia and others (233) that social security schemes require compulsory contributions in order to ensure that the principle of solidarity is applied and that their financial equilibrium is maintained. However, in a recent judgement the ECJ specified that the exclusion from the insurance directives only applies to public social security institutions (234). If a compulsory statutory scheme of social security is administered by private insurance undertakings operating at their own risk with a view to profit, as for the Belgian social security scheme for accidents at work, it is subject to the third non-life insurance directive. This case is even provided for specifically in Article 55, which allows Member States by way of exception to require from private insurance companies offering compulsory insurance against accidents at work and, operating at their own risk, compliance with specific national provisions, except for provisions concerning financial supervision.

The question remains whether the same reasoning could apply to compulsory health insurance, especially if public or non-profit social security institutions are operating in a more market-oriented context, as instituted by different social security reforms in several Member States, or if they would compete directly with private commercial insurers offering substitute forms of protection to categories authorised to opt out of social security.

This issue directly influences the current debate on the future reform of the Dutch health insurance system. The goal of reform is a more efficient and demand-driven health care system in which accessibility and solidarity prevails. On the insurance side, the idea is to integrate the different schemes into one compulsory basic scheme, based on mandatory acceptance by the insurer and premium uniformity. In previous advice, the Dutch social-economic council (SER), a tripartite advisory body, promoted the idea of a private health insurance with social safeguards and administered by private insurance companies. However, the Dutch reform plan (235) finally
chose a public framework of health insurance. This was inspired by more recent advice from a special government commission, which warned against a private model as it would entail application of the European insurance directives (236).

**The general good exception**

The existence of statutory health protection and the way it is organised also influences the demand for private voluntary health insurance. For this reason the form of voluntary health insurance, as well as the way in which it is regulated, is very different from one country to another, since it is essentially filling the gaps left by public health care protection.

The need for regulation in voluntary health insurance has traditionally focussed on substitute forms, providing private cover for persons excluded or exempted from statutory protection. This kind of voluntary health insurance is offered in Germany and the Netherlands, where some professional categories earning high incomes use private insurance. Given its importance, governments have traditionally intervened in this area to ensure that no one would stay without any coverage.

When establishing the rules for integrating insurance markets, European legislators have recognised the particular nature and social consequences of health insurance contracts that partially or completely substitute to health cover provided by the social security system. Therefore, under Article 54 of the third non-life insurance Directive, Member States are authorised to adopt or maintain specific national requirements imposed on insurers in order to protect the general good (237). As reminded by recitals 22-24, such provisions must be considered necessary, proportional and non-discriminatory to ensure access to private health cover irrespective of age or risk profile. Measures that can be justified on this basis comprise open enrolment, community rating, life-time cover, legally fixed standard policies as well as participation in loss compensation schemes. Specifically for the German situation, Article 54 (2) explicitly allows regulating substitutive health insurance according to life assurance techniques.

The question as to how extent Member States can rely upon this provision of Article 54 to justify national regulation in the field of voluntary health insurance is far from clear. The interpretative Communication issued by the European Commission on the concept of general good in insurance business (238) did not add much in this respect.

Obviously, as was stated explicitly in recital 25, the German speciality clause, prohibiting the simultaneous transaction of health insurance and other insurance branches, can no longer be justified by the general good principle, even if it was tolerated for many years. Since the rule of specialisation, under German social law, still applies for insurers based in Germany, the European Commission has sent a reasoned opinion to the German government for infringement of the Directive.

Less clear is the sustainability of more subtle forms of regulation, such as the Dutch Medical Insurance Access Act (WTZ), organising a publicly designed private standard substitutive policy and pooling its financial risk among all insurers financed out of a special contribution paid by all private policyholders (239).

The challenges are even greater when leaving the scope of substitute health insurance and entering the field of complementary or supplementary health insurance, which covers services or providers excluded fully or partially from the scope of social protection. In order to preserve the principles of its former open system of complementary health insurance in the face of an integrated European insurance market, Ireland relied upon the general good exemption to
establish a regulatory framework and a level playing field for all voluntary health insurers. The 1994 Health Insurance Act sets out three main principles for voluntary health insurance to be respected by all insurers: community rating, open enrolment, life time cover. In support of these principles, the government announced the creation of a risk equalisation scheme based on age, gender and prior utilisation by June 2002, to compensate for the possible effect of risk selection. This issue is heavily contested among competing health insurers (240).

Commercial insurers vs. mutual health funds

The specificity of mutuality

Besides the differing material scope of the insurance directives, obscurity also exists as to the types of operators falling under its application. It seems that neither the legal status of the operator, nor the non-profit or profit orientation, are relevant in this respect. Every undertaking developing an economic activity of insurance, “normally provided for remuneration” (Art 50, EC Treaty), is subject to the internal market for insurance services. However, the activity of insurance is not further defined. All this is likely to blur the application of the insurance directives, especially for mutual health funds.

Mutual health funds have traditionally played a vital part in the field of health care cover, even before the existence of social security (241). However, their role extends beyond the scope of insurance, which distinguishes them from private commercial insurers. Generally, mutual benefit societies can be characterised as personal non-profit associations, based on individual affiliation (membership), providing social services and protection, democratically defined by the members and financed in solidarity, with a view of mutually improving social conditions. Accordingly, they are committed to guarantee open enrolment, lifelong affiliation and non-selection of risks. As personal societies, mutual health funds operate essentially according to the principle of self-governance, where stakeholders directly participate in defining the funds’ policy. This feature is regarded important for creating a specific dynamic essentially driven by patients’ interests, adapting the services to actual needs.

Although mutual health funds and for-profit insurers traditionally operated in different segments of the market, the new emerging need for complementary or alternative cover as well as the creation of a European integrated market for voluntary health insurance increasingly tends to create conflicts. The open unregulated confrontation of these different approaches of protection certainly is detrimental for solidarity-based insurance, as so-called good risks would be drained from this pool by risk rating insurers and would therefore lead to premium increases for the remaining higher risks. By being put on the same footing as “classic” commercial insurers, a real threat exists of “cannibalisation” of mutual health funds and a forced drifting towards common market practices, as has happened in the USA (242). This could have serious consequences for patients, especially those presenting higher health risks.

The maladjustment of the insurance directives for mutual benefit societies

The difficulty of integrating mutual health activities into the narrow concept of insurance, while preserving the specific nature of mutuality, has been demonstrated by the troublesome transposition of the insurance directives in the French ‘Code de la mutualité’. In 1992 the French government took the initiative of inserting the ‘mutualité’ as one of the French legal forms an insurance undertaking can adopt to be authorised to provide insurance services throughout the European Union (243).
Besides the more general problem for individual mutual health funds of meeting the financial requirements, several other factors seem likely to put the specific character of French mutual health funds at risk.

- the contractual relation between insurer and insured quite profoundly differs from the membership in a personal, democratically structured personal society;
- the obligation to "limit its objects to the business of insurance and operations directly arising therefrom, to the exclusion of all other commercial business" would prohibit the French mutual health funds from managing within the same legal structure own social and health care facilities, through which they provide services in kind to their members.
- the prudential obligations combined with the freedom of insurance services, would not allow restriction of reinsurance or transfer of portfolios solely to other mutual health funds, unless this could be justified by reasons of general interest. This could seriously affect the autonomy of mutual health funds in defining guarantees and preserving their specific principles of mutuality.

The incomplete transposition of the third non-life insurance Directive into French law during the period defined by the directive finally led to France being condemned by the European Court of Justice (244). Based upon moves to resolve the deadlock, entrusted to former Prime Minister Michel Rocard (245), the French government ultimately enacted a revised Mutuality Code, which incorporates the Community directives while respecting and modernising mutuality principles (246). To link the legally separated insurance activities with health care benefits in kind, the concept of “twinning organisations” (mutuelles et unions soeurs) was instituted, with partially overlapping boards of administrations and limited financial commitments towards each other. To preserve the specific mutuality character, the general assemblies are entrusted with decisions on transfer of portfolio and reinsurance. The specific (contractual) relationship between the member and his or her mutual health fund is indicated by the signature of an affiliation booklet. Also the status (rights and duties) of the elected administrator is set out. Finally, the specific mutuality principles are instituted in law: absence of medical selection, non-individualisation of premiums according to health status and life-time cover.

**Unfair competition?**

In recognition of their social mission and their specific commitments towards their members, mutual health funds are often granted a specific status by law. These national laws explicitly refer to their more comprehensive role, including their involvement in activities related to prevention and health education, social cohesion, solidarity and reducing social inequalities in health. Accordingly, mutual health funds are sometimes awarded tax advantages. This different fiscal treatment is increasingly challenged by private for profit insurers as market distortions and unfair competition. Member States are under pressure to justify the advantages they permit.

Under EU competition law, any practice or preferential treatment likely to distort competition and affecting trade between Member States is, in principle, outlawed (Articles 81-89 EEC Treaty). Anti-competitive behaviour or measures can however be justified if they serve a higher cause (Articles 81 (3) and 87 (2)-(3) EEC Treaty) or if they are deemed to be necessary for preserving a specific task of general economic interest entrusted to undertakings (Article 86 (2) EEC Treaty). The relevance of the latter exception for the health sector is acknowledged, more particularly for certain activities performed by sickness funds (247).

Acting upon a older complaint lodged against French tax exemptions in the field of voluntary health insurance based on the non-profit status of the operator, the European Commission recently urged the French government to abolish these advantages, since it considered them
disproportionate to the need to compensate for the real burden related to services of a general good, which would only represent a minor fraction of activities. This confirms the Commission’s practice to tie down services of general economic interest within clearly circumscribed limits.

But mutual health funds are also accused of abusing from the dominant position they take in compulsory insurance (248). In Belgium, one of the leading mutual health funds, administering compulsory health insurance for 10% of the population, was sued for providing a complementary hospital insurance service to all its members, guaranteeing full cover of patient payments in excess of fixed amount. This service is based on principles of solidarity: all affiliated members are automatically enrolled, no medical or age-related exclusions are applied. According to the Belgian Arbitrage Court, the service fits within the mutual health funds’ statutory mission: providing complementary service in the field of health, while administering compulsory health insurance, all aimed at promoting health and well-being of its members. It is however very likely that this case will end up before the European Court of Justice.

**Towards a broader social concept of general interest in voluntary health insurance?**

The construction of European economic integration is essentially based on the assumption that the market economy is the ideal instrument for ensuring best quality services and goods at the best price. However, this assumption is not always compatible with the specific features of a particular sector nor with the specific political objectives pursued. The challenge facing publicly funded systems, together with increased interest by private insurance companies to develop activities in the health care sector, have given impetus to discussions on regulating the field of voluntary health insurance. It is now considered to play an increasingly important role in complementing the statutory healthcare system, so further regulatory developments are considered necessary to ensure that the market for voluntary health insurance works efficiently and allocates resources in a more equitable manner (249).

In his mission report Michel Rocard advocated the institution at a European level of common rules of general good, applicable to all operators in the field of voluntary health insurance, to preserve solidarity and accessibility in the field of health care. On his initiative as an MEP, the European Parliament adopted a Resolution on supplementary health insurance (250), calling on the Commission to examine the possibility of a framework for supplementary health insurance schemes. Referring to the increasing importance of voluntary health insurance in realising the fundamental right of access to quality health care within reasonable time limits, the resolution suggests some minimum rules to be observed by all private insurers, non-profit as well as for-profit, to prevent discrimination on financial or medical grounds: prohibition on the use of personal medical data (e.g. genetic typing) or prior medical screening (except a medical questionnaire), lifelong insurance (with portability), transparency as to foreseeable changes in premiums, organising a pooling system to cover the cost of serious diseases (catastrophic diseases), etc.

Referring to the incorporation into the Community framework of the fundamental right on access to health care and the need to ensure a high level of health protection, the Resolution insists on the need to develop a common view of universal services in the light of the Amsterdam Treaty and calls on the Commission to propose appropriate legislative initiatives aiming at the recognition of a common concept of basic service, based on the Community principle of general interest, enabling every European citizen to have access, in his or her country of residence, to necessary and high-quality care within reasonable time limits.
It seems clear that the concept of general interest in the field of health care extends beyond the scope of 'traditional' social security. In its updated Communication on services of general interest in Europe (251), the European Commission states that "many activities conducted by organisations performing largely social functions, which are not profit-oriented and which are not meant to engage in industrial or commercial activity, will normally be excluded from the Community competition and internal market rules". This is confirmed by the ECJ, which ruled that mandatory membership of a pension fund (252) or a substitutive health insurance (253) established by collective labour agreement between the social partners in a sector of industry is not a matter covered by EC competition law. In the opinion of the Court, "the social policy objectives pursued by such agreements would be seriously undermined if management and labour were subject to Article 85(1) of the Treaty when seeking jointly to adopt measures to improve conditions of work and of employment".

In between public statutory health protection and private insurance, there is an area where principles of general interest prevail to ensure accessibility to care irrespective of financial or health status. As this extends to fields of complementary insurance, especially for lower income and high risks groups (e.g. the French couverture maladie universelle), it seems questionable if Article 54 of the third non-life insurance directive provides sufficient legal basis to justify an exemption based on the general good exemption. Therefore, there is some pressure to develop a fourth generation of insurance Directives, creating a wider regulatory environment for human and social risk insurance, binding on all insurers, in order to prohibit any selection of risks, to offer permanent health insurance and to rule out the possibility of any cancellation of contracts due to age or state of health (254). Others claim legal recognition for private not-for-profit social services, possibly by introducing a general exemption for such services on the basis of general interest in Article 16 of the EC Treaty (255).

Conclusion

The whole European legal framework for insurance is essentially based on a logic of free Community-wide competition among insurers whose solvency is guaranteed by the competent authorities of the home Member State, based upon a harmonised set of business conditions and prudential rules. Basically, governments are no longer allowed to materially regulate prices and conditions of insurance products, as this could impede fair competition among European insurers and could jeopardise the financial health of insurance undertakings.

In the field of health care this seriously reduces Member States' possibilities to develop a policy of promoting voluntary health insurance based on solidarity principles. Even if Article 54 of the third non-life insurance directive, introduces a possibility of exemption based on the general good, it seems unlikely that this would meet the regulatory needs felt in different Member States. In order to prevent inequities resulting from the one-sided approach of the insurance market integration process, co-ordination between the different policy areas is needed, especially since Art. 152, 1 of the EC Treaty, introduced by the Amsterdam Treaty (1997), obliges all Community policies "to ensure a high level of health protection".
CHAPTER 7: EU COMPETITION LAW AND HEALTH CARE SYSTEMS

Introduction

A series of judgements by the European Court of Justice (ECJ) have now clarified that, while social security systems enjoy some protection, they are not entirely exempt from competition law. This chapter explores the extent to which European competition law applies to activities pursued by institutions within health care systems. It begins by asking whether, and to what extent, such institutions are “undertakings” and thus subject to European competition law. Second, it examines the nature and scope of activities that such an institution is prohibited from performing by European competition law. It then examines when, even if the institution is considered an undertaking and infringes European competition law, whether its action might be exempt from the scope of competition law because it is in the field of health care. Finally, it examines the extent to which transactions involving health care insurers and providers are subject to laws relating to financial subsidies.

The status of health care institutions as undertakings

The EC Treaty does not actually define the term “undertaking”. By custom and practice, whether something is an undertaking depends on its function. Thus, an undertaking, within the meaning of European competition law, is any entity that engages in an economic activity, regardless of its legal status and the way it is financed.

The ECJ has ruled that it is not necessary for an entity to seek to make a profit to be considered as an undertaking, so non-profit or charitable organisations may be considered as undertakings. Similarly, its ownership, legal form, or incorporation under public or private law are not relevant, so the term can apply to publicly owned enterprises as well as to public corporations or other associations engaged in business activities. Finally, undertakings are not only individual service providers, such as physicians, (public) hospitals, pharmacists and manufacturers of pharmaceuticals or technology; associations of organisations, can also be undertakings.

When is a health care institution not an undertaking

Essentially, the grounds for considering a health care institution as not being an undertaking are that its activities are not economic, but instead are, sovereign, social, non-remunerative, or “purely to meet need”. Thus, exemption from competition law arises solely because an entity is not engaged in economic activity. It is, however, widely, but erroneously believed, that exemption is because the organisation of social security systems is under the jurisdiction of the Member States, and thus a matter for co-ordination rather than harmonisation.

It is true that, under the Treaties, each Member State is free to determine the organisation of its social security system. Issues such as solidarity, compulsory membership, and the distribution of benefits can be decided by Member State. This does not, however, imply that social security systems are beyond the reach of Community law. The ECJ has clearly stated that Member States must observe Community law when organising these systems. Consequently, rules governing competition will apply unless a government structures its system so as the activities of its institutions can be classed as non-economic.

The following section addresses this issue: how should a health care institution act in order to be regarded as non-economic?
**Sovereign activity**

Competition law does not apply where sovereign activities (those necessarily pursued by the State exercising official authority) are performed (264). The limits to such activity were tested in the *Höfner and Elser* Case (265), which examined provision of employment services by the German Federal Employment Office. Although the Federal Office is a public undertaking operating on the basis of public law, the ECJ regarded this as an economic activity. The Court ruled that, simply because employment procurement is normally entrusted to public bodies, it had not always been, and need not necessarily, be carried out by them. As a consequence, it was regarded as an economic activity.

The German Federal government, citing Art. 45 EC, had argued the term ‘official authority’ included all activities in which an institution endowed with State authority interacts with the public through some form of administrative action (266). The European Commission (267) pointed out that the exercise of official authority was a term with a specific meaning in Community law, the content of which did not depend on whether certain activities were performed only by public authorities in some Member States. As private recruitment of executives took place, employment procurement did not involve the exercise of State sovereign power. Thus, an activity that can also be provided by private undertakings as an economic activity cannot be regarded as a sovereign activity.

Following from the judgement in *Höfner and Elser*, health care institutions are not automatically exempt from the scope of competition law just because they hold sovereign rights (268). If their activity is to qualify as sovereign, the decisive factor is whether the activity must necessarily be carried out through the exercise of official authority. A sovereign exemption does not apply, even when a body is exercising official authority, if it trades products or services alongside private undertakings that seek to make a profit (269). This interpretation was upheld in the case of *Haverkate/Huster* (270). Consequently, a state cannot shelter an activity from competition law simply because it is integrated in its sovereign administration (271).

This is illustrated by the example of Germany, where the relationship between health insurance institutions and benefit providers is subject to public law. German health insurance funds have a statutory duty to provide benefits in kind, either through the funds’ own institutions or through external benefit providers at the expense of the funds. Payment for benefits obtained can, as in Austria, be on a contractual basis. Germany, in contrast, has chosen to introduce a system in which doctors are admitted to panels by health insurance funds and associations of physicians acting autonomously. Although these bodies conduct this process under public law, they demand services from physicians. Thus they act as private undertakings and, consequently, are treated as such, and so are subject to competition law, notwithstanding their being acting under public law (272).

**Social activity**

The second possible exemption is where the entity concerned is performing a purely social activity. The definition of social activity has evolved as a result of a series of Court rulings.

In the *Poucet and Pistre* Cases (273), the ECJ identified provision of insurance by insurance institutions with compulsory membership, organised on the basis of solidarity, as a task with an exclusively social character. To determine the social nature of an activity it established a series of criteria: a social function; the principle of solidarity; disregard for the insured persons’ financial situation, their health status at enrolment, and contributions already paid; State control; statutory regulation of benefits; and performance of tasks in conformity with legal provisions. Such
institutions are unable to influence the contribution rate, the use of funds, or the scope of benefit provision.

In the Court’s view, solidarity exists when contribution payments are geared to income and benefits are the same for all recipients, thus leading to redistribution of income and protection for those who would otherwise be disadvantaged by virtue of their financial circumstances or health.

In contrast, the Court has not accepted a social function where social insurance institutions compete with private insurance companies, for example, in the Case Fédération francaise des sociétés d'assurance (FFSA) (274), which involved voluntary supplementary pension insurance. It also considered the provision of compulsory supplementary pension insurance funds to be economic in the Cases Albany (275), Brentjens (276), Bokken (277) and Pavlov (278). These decisions centred on the fact that each system functioned according to the principle of capitalisation. It held that qualification as an economic activity was unaffected even if a social objective was being pursued, there were some aspects of solidarity, or there were restrictions on investments by the social insurance system.

The consequence of these rulings is that health care institutions pursuing social objectives do not have a blanket exemption from competition law. Instead, activities have to be assessed individually as to whether they are social or economic. This will depend on the objective of the activity in question and the manner in which it is carried out.

As noted above, the Court has held that a health care institution operates in an economic way if it competes with private undertakings. However competition law may also apply in some other circumstances. One example is the abuse of a dominant market position, which occurs where an institution exercises control over other trading partners (279).

The distinction is whether a given health care institution acts so differently from private undertakings so that a private company, working in the same way, could not, in principle, hope to make a profit (280). Whether the health care institution actually seeks to make a profit is irrelevant. An economic activity can therefore be defined as one that can be carried out to realise a profit, even if this does not actually happen. An activity that is only possible on a non-profit-making basis is different from an economic one because it is not guided by economic motives but, instead, by the principles of solidarity and of social protection (281).

The existence of social protection is indicated by a statutory insurance obligation and disregard of individual risks. The more pronounced the principles of solidarity and social protection, the greater the manifestation of an activity’s social character. Whether social or economic criteria predominate is decisive.

**Purchasing care**

The social issues explored so far relate to the supply of insurance benefits, not the purchase of health services. Where the funder of health care (insurance organisation or health authority) acts as a purchaser, then different considerations may apply. Obviously, where there is no remuneration, as in tax-based systems with no purchaser-provider split, competition law will not apply. In other situations, each activity must be examined on its merits (282); as previously noted, an organisation is not exempt from competition law simply because some of its activities have a social characterk.

k For a separate view on insurance activity and benefit provision, and an exemption from the scope of application of competition law limited to insurance activity, cf. Zechel, Die territorial begrenzte
Where a funder purchases health care on behalf of the population for which it is responsible, this will primarily reflect economic and not social concerns, even when the purpose underlying its activities is to achieve social goals. The decisive issue is purely whether the institution engages in an economic activity in the same way as a private undertaking. It may, however, claim exemption if it can show that the economic task it performs is in the “general interest” and it would be obstructed in doing so by the application of competition law (see later).

**Remuneration**

A further issue that must be taken into account is whether remuneration (the transfer of an identifiable payment) takes place (283). It does not matter whether payment is made by the recipient of the service or by a third party (284): in the Höfner and Elser Case (285) the ECJ held that an economic activity existed even though the cost of employment placement was not borne by the job seeker (286). The decisive factor is whether the service is provided completely free of charge. In the Humbel and Worth Cases, the Court took the view that public education in State schools and universities was not for remuneration (287). It argued that, by establishing and maintaining a national education system, the State did not seek to engage in profit-making activity, but was merely fulfilling its duties towards its citizens in the social, cultural and educational spheres by means of a system financed essentially from public funds. The implication of this ruling is that provision of health care benefits where no identifiable payment takes place, as is common in tax-financed national health services, is subject neither to legislation on freedom to provide services or on competition (288).

**The “mere coverage of need” by the public sector**

The final ground for exemption from competition law is where the activity is the “mere coverage of need”, by the institution concerned and resources obtained are not subsequently traded. This applies to both private and public undertakings, if they are end users and merely cover their personal needs.

Such activities include activities in which the public sector does not compete as a private undertaking with other private undertakings, but only procures marketable products to maintain its own functioning (289). The State thus merely takes part in the workings of the economy as a consumer; the products and services it demands simply satisfy the relevant authority’s own requirements and do not entail any further participation in economic processes (290).

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In Case C-155/73 Sacchi [1974] ECR 409, para. 14, the ECJ ruled that although a Member State may have granted, for non-economic reasons of public interest, one or several broadcasting establishments the exclusive right to broadcast television and radio programmes, these establishments are nevertheless subject to competition rules in performing their task if that task involves activities of an economic nature.
Ebsen (291) takes the view that this applies in tax-financed national health systems, where health care benefits are provided by State authorities as genuine benefits in kind. He compares this with procurement of learning material by schools which are then distributed to pupils. He does, however, contend that this model of State procurement does not apply to the benefit-in-kind system in German health insurance schemes, for two reasons. First, he argues, what appears as a ‘benefit in kind’ has been converted by the insurance funds to a legal construct, turning the direct economic transaction between benefit providers and the insured into a triangular benefit relationship. Second, he contends that statutory health insurance schemes are organised as provident-provision systems. Insurance funds thus act, in economic terms, as mediators between benefit providers and ultimate recipients. He therefore argues that German health insurance funds cannot be viewed simply public consumers (292). He also notes that, although public procurement is not subject to competition law in the narrow sense, it is constrained by regulations governing the award of contracts.

**Conduct prohibited by European competition law**

European competition law prohibits cartels (Art. 81 EC) and the abuse of a dominant position on the market (Art. 82 EC). Both have implications for health care.

**Cartel prohibition**

An anti-competitive cartel is characterised by one or more of the following features: prohibited forms of co-operation between undertakings, restraint of competition, restraint of trade between Member States, and existence of a perceptible impact. Prohibited cartel agreements are automatically void under Art. 81 (2) EC.

### Prohibited co-operation

All agreements between undertakings, decisions by associations of undertakings and concerted practices that may interfere with competition are prohibited. All involve the conscious and deliberate co-operation between several legally independent undertakings that thus strive for, or bring about, co-ordination of their competitive conduct (293). The term ‘agreement’ includes legally non-binding arrangements (so-called ‘gentlemen’s agreements’) (294). Decisions by associations of undertakings include recommendations that are binding on their members or are observed by them (295). Concerted practices (296) cover agreements and decisions which are not legally binding, as well as other forms of conscious and deliberate co-operation among undertakings (297).

### Restraint of competition

Restraint of competition exists where activities “have as their object or effect the prevention, restriction or distortion of competition within the common market”. Thus, competition that would otherwise exist must be impaired by a restriction of the economic freedom of action of one or more parties (298). Art. 81 EC protects competition of all types, including not only restrictions and distortions of competition between parties to agreements, but also of competition between each party and third parties. Thus, the prohibition of cartels applies both to ‘horizontal’ agreements that restrict competition between undertakings at the same stage in the economic process and to ‘vertical’ agreements between undertakings operating at different stages of the process which therefore do not compete with each another (299). The question of whether action that impairs a third parties’ freedom to compete constitutes a restraint of competition is unresolved (300). This prohibition includes distortions of both supplier and demand competition (301) and both product
and services (302). With demand competition the key issue is whether the supplier’s economic scope of action is restricted (303).
A restraint of competition must arise, at least partly, from a specified agreement, and the existence of a further restraint as a result of measures undertaken by the State does not mitigate it (304).

Art. 81 (1) EC lists specific examples of prohibited modes of conduct. These include actions that “directly or indirectly fix purchase or selling prices or any other trading conditions”. Prohibited price agreements include fixing prices (305) or actions which “limit or control production, markets, technical development, or investment”. They have in common agreement to restrict competition in terms of quantity and quality (306).

**PERCEPTIBLE IMPACT**

The ECJ has consistently held that the scale of the impact of restraint of competition is relevant (307), so exempting minor cartels. As a consequence, the European Commission has issued a non-binding notice (308) that prohibition of cartels will, as a rule, not apply if the aggregated market shares of all parties involved do not exceed 5% in any of the markets concerned (in the case of horizontal agreements) or 10% (in the case of vertical agreements). However, this does not apply if the restraints of competition are especially grave. For horizontal agreements, this is where there are price-fixing agreements, market partitioning arrangements, and restrictions on markets or production; for vertical agreements it is where there are agreements fixing resale prices and territorial protection arrangements (309).

Although individual ECJ rulings focus on specific cases, it can be inferred from the accumulated case law that the Court also accepts a threshold of 5% of market share (310). The Court does, however, take account of potential as well as actual impact (311).

**EXEMPTIONS FROM PROHIBITION ON CARTELS**

Actions otherwise prohibited by Art 81(1) EC can be permitted by Art. 81 (3) EC if the agreement in question contributes to enhancing the production or distribution of products or promoting technical or economic progress. Consumers must be significant beneficiaries. Restriction of competition must, however, be necessary to achieve the desired objectives.

Art. 81 EC applies only where undertakings actively promote cartels (312). If sovereign measures adopted by Member States make a restraint on trade inevitable, the undertakings involved cannot be held responsible. (313).

In a series of decisions, the ECJ has recognised other circumstances in which constraints on trade may be lawful (314). Many of these involve statutory associations acting in the public interest, especially where the association involved is independent, to a considerable extent, of the undertaking affected, and is pursuing social policy objectives (315).

**Abuse of a dominant position**

For Art. 82 EC to apply requires that one or more undertakings hold a dominant position within the common market or in a substantial part of it. This is considered to exist if its economic position enables it to prevent effective competition, allowing it to act independently of its competitors and its customers (316) (317). A group of undertakings may occupy a dominant position even if, while not forming a cartel, they are so closely affiliated that they can effectively act independently of competitors (318). The market concerned is defined in terms of the product or service involved and the geographical region involved (319).
Whether a dominant position is being abused is determined by whether the actions of the undertaking are considered to remain within the admissible bounds of competition (320). In practice, abuse is restricted to exploitation of trading partners (321), such as imposing directly or indirectly, unfair prices or other trading conditions or applying different conditions in similar transactions with different parties and so placing them at a competitive disadvantage (termed “exploitative abuse”).

Art. 82 EC also prohibits the abuse of a dominant market position to obstruct competitors (so-called obstructive abuse) (322). This occurs where suppliers or their associations contribute to quality standards in a way that places foreign suppliers at a disadvantage (323).

The ECJ also considers Art. 82 EC to be infringed where an undertaking attempts to extend the monopoly it enjoys in a particular market to other markets without clear justification (324).

**Exemptions from the prohibition of abuse**

Art. 82 EC, only applies to actions that undertakings take on their own initiative (325). Consequently they must have scope to determine their own behaviour, which they do not if their behaviour is dictated by national legal provisions (326).

Other forms of conduct, not stipulated in the examples contained in Art. 82 EC, may be considered abusive under a general clause (refusal to do business) only if further factors apply, including lack of objective justification, non-proportionality, employment of unfair means, or obstruction of remaining competition (327).

**The responsibility of the State**

Arts. 81 and 82 EC are addressed to undertakings. However, the ECJ has consistently held that Member States must not adopt or retain any measures which impede the practical effectiveness (effet utile) of competition rules (328). This occurs where it requires or favours agreements that are incompatible with Art. 81 EC (329). The key issue is whether an organisation is acting autonomously to create a cartel. The ECJ has held that, where performing the activity is a statutory requirement, the organisation is not autonomous, and therefore its activity is not unlawful (330).

A related question is whether, when it delegates its role to private organisations, the State gives up this protection (331). The Court held that it had not in Reiff and Delta Cases in which the competent public authorities fixed tariffs to promote the general welfare and, if necessary, decided them independently (332). In the Centro Servizi Spediporto and the Librandi Cases, it based its decisions on the fact that the competent public authorities sought opinions from other public and private institutions (333).

Where there is a question of abuse of a dominant market position by public undertakings, rulings imply that Member States are not only prohibited from adopting measures that lead to an infringement of competition law by market-dominating undertakings (334), but that they must not take any measures that would violate Art. 82 EC (335). It is thus irrelevant whether or not the undertaking concerned was a party to the abuse through an autonomous business act.
Do health care associations form cartels?

In many health care systems, institutions form associations that are entrusted with widely differing tasks. For example, they decide on whether to engage with benefit providers or make arrangements with providers’ associations. In addition, many recommend standard business conditions to their institutions. Do these activities represent cartels?

The decisive factor is whether or not such associations have scope for autonomous business activities. This will not be the case, for example, if national regulations stipulate who must be accepted as a benefit provider, so that the association merely enforces statutory regulations without any scope to influence the selection process. Conversely, if anti-competitive co-operation is simply accepted or facilitated by the State then the prohibition on cartels will apply (336), even where such action is subsequently sanctioned by sovereign measures and declared binding (337).

It is likely that the prohibition of cartels will not apply where decisions can only be taken by health care associations rather than their constituent institutions, or where the structure of the health care system is such that the association and its institutions form a single economic unit. In such cases, the institutions lack the economic autonomy needed to enter into a prohibited cartel agreement and their co-operation is not deemed to be a ‘decision by an association of undertakings’. However, while the health care association cannot be accused of creating a prohibited cartel, it may be guilty of abuse of a dominant position.

Conversely, if individual institutions, rather than just the association, are able to make autonomous decisions, a cartel will be created, provided the relevant decisions are binding on the institutions involved, or are observed by them.

Finally, a resolution adopted by a health care association cannot be deemed a prohibited cartel if the members of the institutions involved cannot be regarded as representatives of those institutions. This will be the case if implementation of the resolution takes account of not only the interests of the institutions, but also those of the general public or benefit recipients, as might occur when taking account of the interests of a rural population in determining the distribution of physicians (338). The same will apply if those participating in the decision are independent of the institutions or if a majority in the decision-making body are representatives of public authorities (339).

There remains the question of the State’s responsibility. National regulations that require health care associations to conclude or favour prohibited agreements are incompatible with the Treaties. The State only acts unlawfully if it deprives a regulation of its State character by transferring responsibility for intervening in economic processes to the association. In other words, the State cannot delegate sovereign powers of economic regulation to an association (340).

Agreements between health care associations and benefit providers are treated in a similar way and are lawful if the statutory provisions allow no scope for autonomous business conduct. The previous comments on State responsibility for actions involving health associations remain valid.

Restrictions on the admission of panel doctors - abuse of a dominant market position?

Where health care institutions operate as purchasers of health care, they will often, singly or in association, exercise a monopoly. The question arises as to whether this dominant market position is abused if not all physicians are offered contracts with them. If a restriction on admission is based on the decision of an association of health care purchasers or on an
agreement between an association and an association of benefit providers, this may constitute a prohibited cartel.

Marhold (341) argues that, as demand monopolists, health care institutions are obliged to conclude contracts with physicians as they are largely dependent economically on health care institutions because of a lack of other potential markets, and thus a lack of effective demand competition (342). Excluding physicians from the health care market constitutes an abuse unless the action can be justified (343). Thus, restricted admission of panel doctors is unlawful where the selection process is arbitrary or abusive.

Restricted admission of panel doctors may have adverse effects on patients where it leads to a shortage of physicians, especially where number of doctors is obviously unable to satisfy the demand for medical services and if recourse to non-admitted physicians is financially disadvantageous to patients (344).

Restricting markets to the disadvantage of consumers may also arise from imposition of budgets for pharmaceuticals and related goods, such as where costs of exceeding budgets are passed on to patients. The related issue of rationing, where it is to the detriment of medical progress, may also fall foul of the prohibition of limiting technical development to the prejudice of consumers.

**Exemption for services of general economic interest**

Under Art. 86 (2) EC, undertakings entrusted with the operation of services of general economic interest may be exempt from competition law. The Treaty provisions apply only so far as their application does not obstruct the performance of the task assigned to undertakings.

The first prerequisite for an exemption is that the undertaking in question is entrusted by the State with services that are of general economic interest. The criteria for determining the ‘general interest’ are defined in Community law (345) and include health and social protection (346). If, in addition, these institutions also become active in economic terms, their activity can be said to consist in providing services of general economic interest.

The appearance of the term ‘services of general economic interest’ not only in Art. 86 (2) EC, but also in the newly established Art. 16 EC and in Art. 36 of the Fundamental Rights Charter confirms that services of general economic interest occupy a special position within the framework of the European Union.

**Obstructing health care institutions from performing the particular task assigned to them**

For this exemption to apply, the application of competition rules must obstruct the performance of the task assigned to health care institutions. As the relevant Article limits the application of EC Treaty provisions, this provision is construed restrictively (347). It is not sufficient for the task assigned to a social insurance institution to be merely hampered or impeded by observing competition law (348). This task must be ‘obstructed’, with ‘obstruction’ narrowly defined (349). In the Cases Sacchi (350) and Höfner and Elser (351), the ECJ ruled that the application of the provisions must be incompatible with performance of the particular task. Further clarification came in the Cases Albany (352), Brentjens (353) and Bokken (354) where the Court held that an exemption may be valid even if the economic viability of the undertaking is not threatened. Instead, it is sufficient for the application of competition law to prevent the undertaking from performing the tasks assigned to it or to remove certain rights without which it would no longer be economically viable to perform the task. The Commission v France Case (355) introduced the
concept of ‘endangering’ performance of a task, with the English and French versions of the judgment using the terms ‘not be possible’ and ‘faire échec à’ (356) respectively.

The task assigned to health care institutions, as a rule, embraces the provision of accessible, high-quality, low-cost medical care to all those eligible for benefits. Whether a health care institution can only perform this particular task if it contravenes European competition rules will depend on the individual activity concerned, taking account of the specific situation of health care institutions and the special features of the health care market.

The specific situation of health care institutions

Health care institutions differ from other undertakings on account of their inherent social role. If this role is so strongly pronounced that it divests the institutions’ activities of their economic character, they cannot be considered to be undertakings and so will be exempt from competition law. However even those activities not classed as ‘social’, in general, include some social elements. These can reduce a health care institution’s ability to compete with private undertakings. In its decisions on supplementary pension schemes, the ECJ recognised that such constraints could justify giving these funds an exclusive right to manage these supplementary schemes (357).

There are social aspects to both the supply of insurance and health care benefits. As a rule, their impact on relationships with benefit providers is not sufficient to divest such activities of their economic character, unless they have an absolute obligation to provide benefits in kind. Such an obligation makes their ability to demand services less competitive compared with private health insurance undertakings, since their relationship with benefit providers leaves them less scope for negotiations. Their scope for negotiation is also frequently restricted by the need to safeguard contribution stability.

The special features of the health care market

The special circumstances prevailing in the health care sector mean that the health care market is not subject to pure competition. In the usual competitive market, the purchaser bears the financial consequences of his decision based on need. In the health care market, depending on the precise arrangements in force, patients bear none, or only a certain portion, of the cost of any benefits they receive. Furthermore, patients are not classic purchasers as they on decide about the first step, to consult a physician, with subsequent decisions on benefits determined, to a considerable extent, by the physician acting as an agent for the patient (358).

At least in theory, as the cost is not borne by the patient, he or she may demand excessive services while physicians may use their information advantage to maximise profit and create additional demand, which may occasionally be harmful to health (359). This is referred to as ‘moral hazard’ and is tackled by admission restrictions, fixed prices and limits on benefit provision (360). The justification for these restrictions is to avoid an increase in expenditure to the extent that it poses a threat to a health systems’ financial viability.

The ECJ has repeatedly recognised the financial viability of social security schemes as grounds for exemption from internal market regulations. For example, in the Duphar Case (361), it held that Member States were entitled to regulate drug consumption so as to safeguard the financial situation of their health insurance schemes. In the Cases Kohll (362) and Decker (363), the Court acknowledged that a threat to the financial viability of social security schemes could justify a restriction of the free movement of goods and services. Finally, as noted earlier, in the Cases Albany (364), Brentjens (365) and Bokken (366), it considered that exemption from competition
law was justified if the rights in question were necessary for the institution concerned to perform tasks of general economic interest under economically acceptable conditions.

For health care institutions to resort to, say, anti-competitive price fixing or selective contracting presupposes that the means are appropriate and proportional. Restriction of the Treaty provisions may not go beyond what is necessary for performance of the task (367). The Member State need only show that the performance of the particular task is being obstructed; evidence that there is no other way to ensure that the task is performed must be provided by the Commission (368).

Consequently, to the extent that performance of a task is possible without infringing the EC Treaty, health care institutions and national legislators will be bound by it (369). Importantly, where a health care institution is unable or unwilling to perform a task assigned to it in a satisfactory manner, there is no scope for exemption from competition law (370). Thus, a Member State cannot invoke Art. 86 (2) EC to justify restricted admission of panel doctors if the existing system is obviously unable to meet beneficiaries’ demand for medical services, whether because it fails to provide adequate geographical coverage or the quality is inadequate. This indicates that assessment of State measures must consider not only cost, but also include qualitative aspects of health care and access to health care benefits. This may have implications in countries with long waiting lists.

**The development of trade**

Finally, Art. 86 (2) EC requires that the development of trade must not be affected to such an extent as would be contrary to the interests of the Community (371). This requires balancing the national interests of the Member State in performing the task in question through a service institution, on the one hand, and the interests of the European Union, on the other (372). The interests of the Union are inferred from the objectives and principles of the Treaty (373).

The State’s interest in the performance of tasks assigned to health care institutions is counterbalanced by weighty interests of the Community. Thus, restrictions on the admission of panel doctors may run counter, not only, to competition law, but also freedom of establishment and freedom to provide services (374). It is therefore important to consider whether restricted admission of benefit providers is compatible with the fundamental freedoms. A related issue is whether the conditions of contracting discriminate against applicants from other EU Member States (375). A conflict of interest will also arise if contracts with benefit providers are subject to territorial limits. This can imply both a restriction of the passive freedom to receive services on the part of the insured and a direct restriction of the active freedom to supply services by benefit providers resident in another EU Member State. It may also act as a bar on imports of medical products.

If restriction of benefit providers or price fixing is shown to violate one of the fundamental freedoms, it is likely that the Community interests will prevail (376).

**Law on subsidies**

The European Union sees the unjustified provision of subsidies as an important barrier to the development of a single market. Given the many financial transactions in which health care insurers and providers are involved, it is important to understand whether, and to what extent, they may be affected by the relevant laws.

Three decisions by European courts, two by the ECJ and one by the EFTA Court of Law, have examined whether the setting of premiums in the area of social security violates the ban on
financial subsidies. A decision of the ECJ on 29.6.1999 examined the deferment of premiums by a health insurance firm in respect of a shipping firm that had sought bankruptcy. Ultimately the bankruptcy proceedings were not averted, despite the deferment of premiums, and it was asked whether the deferment of premiums constituted a prohibited subsidy. Competition had been distorted because the shipper, even though already bankrupt, could continue to run its business because the health insurer did not seek payment, so it was able to compete unfairly with other businesses that did have to pay premiums.

The ECJ interpreted the deferment of premiums as a financial subsidy according to Art 87 Section 1 EC. The issue was whether the organisation received an economic benefit that it would not have received under normal market conditions. The definition of “normal market conditions” depends on the “reasonable investors test”. A subsidy does not exist if a private investor would have given financial aid in the same circumstances. If this is not the case, a prohibited subsidy may exist. The ECJ concluded that, in these circumstances, the shipper was unlikely to have been able to attract a loan from a private investor. The sole source of financing was the deferment of health insurance premiums, which were therefore considered to be a prohibited subsidy.

Other decisions have examined state support for certain economic activities through favourable premium payments. The case of Maribel involved Belgian government programmes that sought to protect some businesses that were especially vulnerable to global competition. Amendments of the legal framework allowed businesses in the transportation, mining, chemical manufacturing, and metallurgy sectors to benefit from reduced premiums, of up to 9,300 Belgian Francs (€230) per employee per quarter. The Commission view that these reductions in social insurance premiums were inadmissible state subsidies was upheld by the ECJ. In a similar case the EFTA court examined the payment of premiums in northern Norway where industrial development was encouraged by lower social premiums than in the rest of the country. This, too, was judged by the EFTA court to be an unlawful subsidy. It is remarkable that Art 87 EC does not recognise an exemption of the scope of the financial subsidies law for the benefit of social institutions. This can attain special importance for the financing of health care institutions.

This may have implications for hospitals where a general deficit is covered without consideration of the performance of this hospital. This could create a distortion of competition between hospitals where such hospitals are considered to be undertakings under competition law.

**Public procurement**

European procurement law seeks to ensure equal access for all enterprises to public contracts. They set out the need for public contracting to be competitive, non-discriminatory, and maximally transparent. They thus apply the fundamental freedoms of the EC Treaty to the areas that have

\[m\] The actual procurement procedure upon revised version of most of the procurement directives is regulated by the Dienstleistungskoordinierungsrichtlinie (service directive) 92/50 (ABI 1992 L 209/1), by the Lieferkoordinierungsrichtlinie (supply directive) 93/36 (ABI 1993 L 199/1), by the Baukoordinierungsrichtlinie (construction directive) 93/37 (ABI 1993 L 199/54), as well as by the Sektorenrichtlinie (sectors directive) 93/38 to coordinate the award of contracts by the contract awarders in the field of water, energy, and traffic supply, as well as in the telecommunication sector (ABI 1993 L 199/84). The legal protection possibilities in the procedure of awarding contracts are regulated by the Nachprüfungsrichtlinien (verification directives) 89/665 to coordinate the legal and administrative provisions for the application of the verification procedures within the scope of the procurement of public supply and construction contracts (ABI 1989 L 395/33) and 92/13 to coordinate the legal and administrative provisions for the application of the Community rules in the field of the Sektorenrichtlinie (sectors directive) (ABI 1992 L 76/14).
held out longest from the market (377). The directives set out verifiable obligations by contract
awarding parties to guarantee the equal treatment of all enterprises applying for public contracts and the
transparency of the procurement procedure. The economically most advantageous offer must be
awarded the contract, even if it comes from a different Member State (378). The contractors can
invoke their rights at national level (379).

In principle, the procurement directives cover only those contracts whose estimated total values
exceed certain threshold values. Where the threshold value are not reached the special
procedural provisions of the directives are not valid, but the general provisions of the EC Treaty
remain applicable (380).

Those awarding contracts that are subject to the directive include the State, regional (and/or
local) authorities, institutions governed by public law, and associations that consist of several of
these corporate bodies or institutions (381). In this connection the term “State” must be
understood not in an institutional, but in a functional meaning (382). The ECJ also includes in this
term such contract awarders that are not formally integrated into the state administration, but are
nevertheless active in the name of the State or of a regional or local authority (383). Each
institution with legal personality that was founded for the special purpose of fulfilling non-
commercial or non-industrial tasks, but which are according to general interest, and which is
financed or controlled predominantly by the State, by regional or local authorities, or other
institutions governed by public law is considered as an institution pursuant to public law (384).
The term “institution governed by public law” also has to be understood in a functional way. It
includes institutions organized according to private law, because otherwise it would be possible
for Member States to evade the scope of the procurement directives by transfer of undertakings
into private ownership (385).

**Are Health Care Institutions Covered By the Scope of Application of the
Procurement Directives?**

As a rule, health care institutions are deemed to be public contract awarders within the meaning
of the procurement directives. In the first instance, those health care institutions that are
considered as social (see section on “social activity”) according to the criteria developed by the
ECJ in relation to competition law are also to be deemed as institutions established for the special
purpose of fulfilling tasks of general interest and non-commercial or non-industrial tasks. As
regards the qualification as institution pursuant to public law it is of no consequence whether the
health care institution is active economically as well as socially. The ECJ takes the view that the
status of a body governed by public law is not dependent on the relative importance, within its
business as a whole, of the meeting of needs in the general interest that do not have an industrial
or commercial character (386). The fact that meeting needs in the general interest constitutes
only a relatively small proportion of the activities actually pursued by that entity is irrelevant,
provided that it continues to attend to the needs which it is specifically required to meet (387).

The list of institutions governed by public law also contains in Annex I of the Directive 93/37n
various national health care institutions. Though not exhaustive, that list is intended to be as
complete as possible and is taken into account by the ECJ when checking if the respective tasks
have an industrial or commercial character or not (388).

Thus on principle, procurement law is applied when health care institutions make purchases for
their own purposes, such as equipment and buildings.

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n Although this list is annexed to Directive 93/37/EC, all other public procurement directives refer
to it.
The characterisation of the activities of health care institutions is more problematic in relation to contracts for medical services in systems providing benefits in kind. Such contracts are framework contracts in which the providers of services obligate themselves to provide certain services for patients on account of the institution. This way the health care institution makes available benefits in kind to the patients entitled to them. Then, in case of need, the patient expresses a concrete demand for a service. This demand leads to payment of the remuneration agreed in the framework contract. Consequently, this is a demand on two levels: the health care institution’s demand that leads to the framework contract, and, on this basis, the demand for services by the patient. From this one could infer that the actual demand is only made by the patient and not by the health care institution. Consequently, it would not be a demand for services by public contract and therefore the procurement law could not be applied (389).

Notwithstanding this, the ECJ applied procurement law in the Tögel case (390). The subject matter was the procurement procedure for a contract concerning ambulance services that was covered by the Service Directive. The contract awardee was an Austrian health insurance carrier. The application of the procurement law remains applicable even when no single contract reaches the financial threshold, if the individual contract forms part of a series of linked contracts whose total value exceeds that set out in the directive (391).

In the case of health care institutions that provide benefits in kind the ECJ applies the provisions governing the award of public contracts on the first level, i.e. on the level of framework agreements between the health care institutions and the performers of services (392). This opinion results in the application of both competition and procurement law are applied. This also finds expression in the jurisdiction of the ECJ. In the previously mentioned Tögel case (393) it applied the procurement law on the demand by a health insurance carrier for ambulance services. The Sodemare case dealt with a social assistance carrier’s demand for health services. The ECJ did not discuss the status of the social assistance carrier as undertaking, but still applied the law on competition. In order to release the health care institutions from these regulations a regulation according to European law would be necessary. This might happen by means of an exemption provision as regards competition provisions in the EC Treaty or by means of an exemption provision in the procurement directives, depending on what course makes more sense.

**Conclusion**

This chapter covers a large amount of complex legal argument, much of which has been developed in sectors other than health care, but which would appear to have direct relevance to the way that health care is organised within Member States. It shows that health care organisations are potentially subject to competition law; they may be considered as undertakings and this is not affected by issues such as ownership of profit-seeking status. What is important is whether they engage in economic activity.

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

There are several ways in which activities may qualify as non-economic. They may be sovereign, in other words necessarily performed by the State when exercising official authority. However, the State must show that it is necessary for it to perform this activity, and must exercise caution when delegating its role to other bodies. It may be a social activity, but here it must demonstrate that it involves social protection and is based on the principle of solidarity. It may also be exempt because it involves no identifiable payment or because the activity simply involves the
organisation concerned meeting its basic needs to continue to function. However, it is easy to see how poorly considered health care reforms, especially where they introduce market-mechanisms and decentralisation, might render organisations unexpectedly subject to competition law.

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

In the absence of a clear statement of principles on which health policy in Europe should be based, the ECJ is bound to base its decisions primarily on the imperative to promote the single market. It does recognise the particular circumstances of health care, such as the need not to undermine national systems, but this chapter demonstrates clearly the need for much more clearly thought out guidance on what the European Union is seeking to achieve when meeting the health needs of its population within a single market.
CHAPTER 8: INFORMATION TECHNOLOGY LAW AND HEALTH CARE SYSTEMS

The potential impact of EU Information Technology law on health care systems

Developments in information and communication technologies (ICT) have serious implications for health and health care systems in the European Union (EU). On the one hand, the proliferation of health-related websites on the internet and the rise of telemedicine, or ‘ehealth’, are significantly enhancing European consumers’ access to information about health and health care. On the other hand, there are growing concerns about the increasing scope of personally identifiable health information about individuals in electronic form, in health databases and through online networks (394).

Since the early 1980s the EU has actively encouraged ICT developments, particularly with regard to the internet, seeing in them opportunities to create new jobs and provide services more efficiently (395). In June 2000, as part of its drive to transform Europe into an information society, the EU launched an initiative known as the eEurope Action Plan 2002. This initiative, largely intended to ensure that European economies do not lose out to international competition in ICT, has three main objectives:

- a cheaper, faster, more secure internet
- investment in people and skills
- stimulation of the internet (of which ‘health online’ is a key component) (395).

Key elements of this action plan include privacy enhancing technologies, harmonised use of smart cards for accessing the internet and development of best practice in electronic health services.

The European Commission envisages the aim of health protection in the information society as ‘to improve public health in the European Union, to prevent human illness, diseases and sources of danger to human health via a new generation of computerised clinical systems, advanced telemedicine services and health network applications’ (http://europa.eu.int/information_society/topics/health/index_en.htm). It emphasises providing support to health professionals, continuity of care, health service management and intelligent systems, and allowing citizens to assume greater participation in and responsibility for their own health.

While these developments in ICT bring with them a wide range of benefits for consumers and health care providers, they also present new legal challenges that have attracted the attention of policy makers at a global, European and national level. Many issues are not specific to health and health care, so it is not always immediately evident that legislation on ICT has implications for the provision of health care. From a health care perspective, however, the most directly relevant legal issues involve questions of consumer protection in three areas: the privacy of identifiable health data (maintaining confidentiality and ensuring data protection); the reliability and quality of health information provided electronically; and tort based liability. Issues that indirectly impact on health care, in so far as they affect health databases, website operators and providers of telemedical services, include ownership and intellectual property rights, and secure transfer of information and financial transactions.

Current EU legislation

In recent years the EU has adopted various legal measures to address all of these issues, the most relevant of which are summarised in Table 7.1.

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Telemedicine is the delivery of medicine (or health care) to a location distant from the provider.
Table 7.1 EC Directives with consequences for the information society

<table>
<thead>
<tr>
<th>Date</th>
<th>Directive</th>
<th>Title</th>
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<tbody>
<tr>
<td>1985</td>
<td>85/374/EEC</td>
<td>liability for defective products</td>
</tr>
<tr>
<td>1992</td>
<td>92/59/EEC</td>
<td>general product safety</td>
</tr>
<tr>
<td>1993</td>
<td>93/42/EEC</td>
<td>medical devices</td>
</tr>
<tr>
<td>1995</td>
<td>95/46/EC</td>
<td>protection of individuals with regard to the processing of personal data and on the free movement of such data</td>
</tr>
<tr>
<td>1996</td>
<td>96/9/EC</td>
<td>legal protection of databases</td>
</tr>
<tr>
<td>1997</td>
<td>97/7/EC</td>
<td>protection of consumers in respect of distance contracts</td>
</tr>
<tr>
<td>1997</td>
<td>97/66/EC</td>
<td>processing of personal data and the protection of privacy in the telecommunications sector</td>
</tr>
<tr>
<td>1999</td>
<td>1999/93/EC</td>
<td>a Community framework for electronic signatures</td>
</tr>
<tr>
<td>2000</td>
<td>2000/31/EC</td>
<td>certain legal aspects of information society services, in particular electronic commerce, in the Internal Market</td>
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</table>

**Data protection**

Confidentiality is vital to any medical exchange. In order to maintain confidentiality in electronic medical exchanges, regardless of the medium employed, computer and telecommunications systems must be secure, all those who handle information must have a high duty of confidentiality, and patients must have the option of verifying any information that is held about them (396). Rapid developments in information technology and the purposes to which personal data are put necessitate new safeguards. Some are, however, pessimistic about whether privacy can be ensured in this new information society (397). At the EU level the following measures have been taken with the aim of ensuring confidentiality in data processing:

- EU directive 95/46/EC on the protection of individuals with regard to the processing personal data and on the free movement of such data’ (European Commission, 1995) (398)
- EU directive 97/66/EC concerning the processing of personal data and the protection of privacy in the telecommunications sector (European Commission, 1997a) (399)

Directive 95/46/EC aims to ‘protect the fundamental rights and freedoms of natural persons, and in particular their right to privacy with respect to the processing of personal data’ (Article 1.1). A related aim is to harmonise data protection legislation in order to facilitate the free flow of personal data between Member States’ of the EU (Article 1.2) (400). Protection is to be provided to the highest standard available under national law within the EU, rather than being a compromise of average standards of national protection (401).

Building on the principles enshrined in the Council of Europe’s 1981 Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, the directive gives individuals basic rights of consent (Article 7), verification and correction (Article 12). Each Member State must create an independent public authority to supervise personal data protection and organisations processing data must appoint a ‘data controller’ who must register with the relevant public authority. The directive applies to all data, including manually held records containing personal information (402), but data collected for ‘purely personal’ or ‘household purposes’ are outside the scope of the directive. Data must be processed fairly and lawfully; collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes; accurate, kept up to date (in certain circumstances), relevant and not excessive given the purposes for which they are stored; and kept in a form which permits identification of
individual data subjects only for as long as necessary for the purposes for which the data were originally collected (Article 6).

The directive also requires adequate measures to be taken to ensure the security of stored data (although greater health relevant guidance on such measures is given in the Council of Europe Recommendation No R (97)5 on the protection of medical data) (396). Article 25 restricts the transfer of personal data outside the EU except where third countries ensure ‘an adequate level of protection’, as judged by the standards of the directive. So far, the United States has been found not to provide an adequate level of protection, posing potential problems for US businesses, particularly those with European operations (403). In July 2000 the EU and the US Department of Commerce reached agreement on a ‘safe harbor framework’ to allow individual companies to operate on the basis of a system that certifies their provision of adequate data protection as defined by Article 25 (www.export.gov/safeharbor).

The sensitivity of personal health data is recognised in Article 8 regarding the processing of special categories of data, which is prohibited unless safeguards are in place (400). Special categories include information revealing racial or ethnic origin, political opinions, religious or philosophical beliefs or trade union membership or disclosing details of a person’s health or sexual orientation. Where personal health data are recorded for research or other purposes, but not used directly in the process of delivering health care, the key issue is of confidentiality; however, where information systems relate to the active treatment of patients, the issue is of the integrity and availability of the patient data required (400).

The degree of harmonisation that the directive can achieve has been questioned, partly because the directive gives Member States substantial scope for derogation, and partly because it does not apply to the processing of personal data in the course of any activity that falls outside the scope of EU law, although this is not defined by the directive (401). In spite of the October 1998 deadline for Member State action, France, Germany, Ireland and Luxembourg have yet to pass legislation implementing the directive (http://europa.eu.int/comm/internal_market/en/dataprot/law/impl.htm).

Directive 97/66/EC regulates privacy in telecommunications (399). It extends certain privacy rights to legal as well as natural persons and applies to data processed in connection with the provision of telecommunications services in public telecommunications networks, in particular via ISDN (396). In 1999 the European Commission launched a review of the current telecommunications framework, leading to a proposal for a new directive aimed at adapting directive 97/66/EC (2000/C 365 E/17 OJ 19/12/2000) (404). The proposal for a directive concerning the processing of personal data and the protection of privacy in the electronic communications sector aims to impose on all electronic communications services (rather than just telecommunications services) the same rules that apply to offline services. It states that the directive ‘should be adapted to developments in the markets and technologies for electronic communications services in order to provide an equal level of protection of personal data and privacy for users of publicly available electronic communications services, regardless of the technologies used’ (Recital 3). The use of the broader term ‘electronic communications services’ suggests that the proposed directive goes beyond directive 97/66/EC, but it is important to note that the existing directive already applies to the internet, so the proposed directive is not as radical a change as might have been expected (404).

A criticism of the proposed directive is that its scope is limited to the provision of electronic communications services ‘for remuneration’, which suggests that internet providers that provide free access do not fall within the scope of the directive.
Ownership of data and intellectual property rights

Although the data protection directive (95/46/EC)(398) specifies that data should only be used for the purpose stated when collected, this duty is interpreted more widely in the area of health care, and further data processing for scientific research purposes may be acceptable, even if not originally declared to the data subject, so long as appropriate care to ensure confidentiality is taken (recital 34) (396).

Directive 96/9/EC on the legal protection of databases attempts to address the issue of who actually owns health related data by improving the previously weak copyright protection for databases (405). Although it is argued that the directive effectively set the global agenda for national and international database protection, going beyond the protection afforded to databases in other areas of the world, notably the United States (406), it is not entirely clear to what extent this increases the protection available to owners of health related databases (396). Thakur also points out several weaknesses in the directive, arguing that it fails in a number of respects to qualify as an optimum global model.

Security and electronic signatures

The electronic signature is a key tool in ensuring confidentiality, integrity and authenticity in the transfer of data between electronic sources (396) (400). It is therefore vital for building consumer confidence in and maximising the opportunities presented by e-commerce (407). Although a whole range of electronic signature tools exist and are widely used, legally they were not widely recognised within the EU prior to the European Commission’s directive on a Community framework for electronic signatures, which aims to establish a legal framework for electronic signatures in order to create a homogenous technology-neutral background for the operation of electronic signatures issued through certification service providers anywhere in the EU (408).

Commentators have, however, noted a number of weaknesses in the directive. First, it does not provide a basis for dealing with electronic, as opposed to paper documents and further legislation is necessary to allow electronically signed documents to be treated in exactly the same way as paper documents (396). Specifically, some national laws still require certain health related documents, such as prescriptions, to be produced on paper. Because the directive does not cover the conclusion of contracts or other non contractual acts (Article 1), Member States are not required to address these issues (396). Finally, the legal issues regarding electronic signatures largely fall on health care providers rather than telecommunications service providers.

Consumer protection in distance selling

EU directive 97/7/EC on the protection of consumers in respect of distance contracts seeks to protect consumers (as natural persons and not in a commercial or professional capacity) from the risks that may arise when they are unable to examine goods prior to purchase or to see the supplier’s premises, as is usually the case with telemedicine and use of the internet (409). Suppliers are required to comply with the duties outlined in the directive in situations where they use one or more means of distance communication to conclude a contract. These duties include the consumer’s right to written information about the supplier and the goods or service, and the right to withdraw from the contract within seven working days from the time at which the written information is supplied, without penalty and without giving any reason. Although this directive is the EU’s key legal text applicable to contracts concluded at a distance, critics claim that it does not provide EU consumers with comprehensive protection, particularly as protection is only granted where contracts are concluded (and concluded at a distance), and does not afford protection to consumers merely surfing the internet (410).
Electronic commerce

The directive on electronic commerce complements the existing laws protecting consumers in the EU and concerns three areas: general information to be provided; commercial communications; and contracts. In terms of general information, the directive goes beyond the distance selling directive by requiring information such as: the name, address and email address of the service provider; the trade register (where applicable) with which the service provider is registered; any activity subjected to an authorisation scheme (where applicable); and (where applicable) the professional body with which the service provider is registered, the professional title granted by the Member State, and the VAT number (Article 5). Prices and essential terms and conditions should also be mentioned (Article 5). For commercial communications the new directive also goes beyond the distance selling directive in requiring the service provider to identify clearly: the commercial nature of the communication; the person on whose behalf the communication is made; and (where authorised) promotional offers such as discounts, premiums, gifts, competitions and games. The electronic commerce directive completes the distance selling directive by defining exactly when a contract is concluded and by informing consumers of the procedure for correcting handling errors (410).

Liability

A further aspect of consumer protection is concerned with preventing consumers from harm by imposing duties on suppliers and producers of goods and services. There have been several EU level initiatives to promote this aspect of consumer protection, although there is currently no EU level legislation that directly states the liability of the telemedicine practitioner, although patients can seek compensation when injured as a result of telemedical treatment under existing laws on medical negligence (396).

Two EU directives do, however, afford consumers some protection in the area of product liability. EU directive 85/374/EEC on product liability establishes the general principle that the producer is liable for damages (411). In order to establish liability there must be a defect in the product and harm to the consumer, regardless of whether or not the defect is the result of negligence on the part of the producer. The directive further stipulates that when the producer cannot be identified, liability will fall on the supplier, so a patient injured by a defective telemedical product would have cause for action against the producer, if identifiable, or the medical practitioner. Because medical practitioners are also consumers, they can take action against the supplier or producer if an injury arose through the use of a defective product used in a reasonable and responsible way. The duties imposed by the directive highlight the importance of stringent product testing, quality control and risk monitoring (396).

EU directive 93/42/EEC on medical devices supplements directive 85/374/EEC by forcing producers of medical devices to comply with the standards set by the European Committee on Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC) (412). The directive covers a wide range of medical products (although it is restricted to devices that are in immediate contact with the human body so it does not cover all telemedical devices), including medical imaging devices (396).

Quality

The tension between access and quality is central to ehealth technologies (413). Ehealth breaks down the traditional single point, gatekeeper model of access, allowing multiple entry points and the direct distribution of information to patients (414). Health related websites are currently among the most frequently accessed sites on the internet. However, while these technologies
may increase access to information and decrease the cost of obtaining it, they present serious issues in terms of quality assurance. The quality of information on the internet is extremely variable and, at the present time, European consumers have very few resources with which to assess quality and authenticity, which may generate public concern and thus inhibit the internet's usefulness (415) (416) (417). A study undertaken to assess the reliability of health information on the internet, looking at parent-oriented web pages relating to home management of feverish children, found that only a few websites provided complete and accurate information for this common condition, suggesting an urgent need to check health information on the internet for accuracy, completeness and consistency (418).

The quality of health information is particularly important because poor or inappropriate information could result in serious injury or even death. However, ensuring quality is a complex issue, raising the following questions:

- what constitutes quality?
- how can it be assessed?
- how can consumers be guided to the best available information?
- how can consumers be helped in appraising information? (407)

In the case of the internet, the issue is further complicated by practical constraints and the currently limited capacity of regulators to exert control over operations in ‘cyberspace’. However, leaving aside these technical and philosophical debates regarding the advantages, disadvantages and possibilities of regulating the internet, the EU has launched several initiatives to improve the quality of health related websites.

**EU initiatives: self regulation**

As well as legislative measures, the EU has promoted voluntary self-regulation as a means of improving the quality and scope of ehealth.

‘Health online’ forms a part of the EU’s eEurope Action Plan 2002 (under the objective of stimulating the use of the internet) and involves the implementation (by the end of 2002) of an infrastructure to provide user-friendly, validated and interoperable systems for medical care, disease prevention and health education through national and regional networks connecting citizens, practitioners and authorities online (419). Further action includes:

- developing quality criteria for health related websites to boost consumer confidence in the use of such sites and foster best practice in the development of sites (by the end of 2001) and to form the basis of future policy tools for assuring the quality of information, such as user guides, voluntary codes of conduct, trust marks, accreditation systems etc
- identifying and disseminating best practice in ehealth services to assist purchasing departments in decision making and establishing benchmarking criteria (as soon as possible in 2002)
- establishing a series of data networks to assist with informed health care planning in Member States (by the end of 2002)
- drafting a communication on legal aspects of ehealth to clarify which existing legislation has an impact on ehealth in order to remove some of the uncertainties expressed by industry about the legal aspects of such commercial activity

MedCERTAIN is another recently launched project (medPICS Certification and Rating of Trustworthy and Assessed Health Information on the Net) funded by the EU under the Action Plan for Safer Use of the Internet with the aim of developing a technical and organisational
infrastructure for a pilot system allowing consumers to access meta-information about health related websites and health information providers, including disclosure information from health providers and the opinions of external evaluators (both associations and individual experts) (420). It is hoped that this system will promote consumer confidence by enabling consumers to assess the quality and reliability of information provided on the internet. The model adopted by MedCERTAIN combines:

- consumer education
- encouragement of best practice among information providers
- self labelling
- external evaluation

While these initiatives are welcome, the difficulties inherent in assuring quality should not be underestimated. For example, developing quality criteria such as trust marks and accreditation systems to rate or label websites (a key element of ‘health online’ and MedCERTAIN) can be problematic. In order to operate efficiently and effectively, rating systems should be set up where the following conditions can be satisfied: the rating system or label should be clearly explained to consumers (for example, through a hyperlink to the rating system’s own website); the label should guarantee the identity of the service provider; only a limited number of labels should be developed; labelling should be undertaken on a voluntary basis and defined in collaboration with professional and consumer associations; the label should take into account existing legal standards as a minimum; it should be surrounded by adequate security measures (410).

The use of quality rating can, however, expose those involved to legal challenges in three areas (414). First, ehealth providers may lodge complaints about negative ratings; second, the rating body might award a positive rating to an ehealth provider that subsequently injured a third party; and third, a rating body might face liability for its own web misconduct. There are a number of examples of legal action against rating bodies in the United States (414). Rating bodies and the legal authorities that endorse them will need to implement effective risk management strategies to ensure that they do not jeopardise their worthwhile attempts to improve the quality of ehealth and reduce information asymmetry.

Codes of conduct and out-of-court dispute settlements are other elements of developing quality criteria under ‘health online’. Article 16 of the electronic commerce directive also specifies that Member States should encourage the drawing up of codes of conduct at European level, by trade, professional and consumer associations or organisations, so as to enforce the principles set down in Articles 5 to 15 of the directive, and that these codes should be accessible by electronic means in the community languages. Codes of conduct can be an effective means of enhancing consumer confidence, but they may need to be accompanied by sanctions against providers that do not comply with a code’s principles. Furthermore, a provider should not be allowed to make reference to a code without complying with its principles.

Article 17 of the electronic commerce directive states that Member States should ensure that ‘in the event of disagreement between an information society service provider and the recipient of the service, their legislation does not hamper the use of out-of-court schemes, available under national law, for dispute settlement, including appropriate electronic means’. Alternative methods of dispute resolution are seen as a complement to the judicial system and aim to provide a solution better adapted to the particularities of electronic communication than traditional court procedures. As the directive notes, out-of-court dispute settlement could be especially useful for disputes on the internet because of their low transactional value and the size of the parties involved, who might otherwise be deterred from using legal procedures. Again, however, this type of settlement should not take place unless certain conditions are fulfilled, including: adequate
consumer information; the explicit consent of both parties to submit the dispute to a third party; the participation of consumer associations in the establishment of rules and / or in the resolution procedure; the ensured neutrality and competence of the third party; and compliance with the legal requirements regarding consumer protection (410).

**Conclusion**

The EU has taken a number of measures to protect consumers in the information society, both legislative and non-legislative initiatives. Many of these measures indirectly affect certain aspects of health care systems, in so far as they concern data and database protection, security in electronic transfers, distance selling, product liability and quality control. As few were initiated with health care in mind, they may suffer from weaknesses that reduce their effectiveness when applied to health care. Some of the non-legislative initiatives do directly concern the quality and scope of ehealth, largely through voluntary or self regulatory action, and while these initiatives are welcome, their task is compounded by the complexities involved in ensuring quality on the internet.
CHAPTER 9: THE WAY FORWARD

The need for a European health policy

This report began by outlining the case for a shared European vision of how health care should be organised. It recognised that Member States vary considerably in the detailed organisation of their health care systems but, underlying all of them, is a common model based on social solidarity and universal coverage. This model has several important features that distinguish health care from a normally traded good. In particular, the European social model is based on a complex system of cross-subsidies, from rich to poor, from well to ill, from young to old, and from single people to families and from workers to the non-active. This model has continued to attract overwhelming popular support, reflecting the historical forces from which it emerged and the deeply rooted values of solidarity in Europe. It also recognises that a market for health care is inevitably imperfect; individuals may not always be in the best position to assess their health needs, whether because they are unaware of the nature of their health need or are simply unable to voice it effectively. Health care is increasingly complex, creating major information asymmetries that open up scope for exploitative opportunistic behaviour by providers and thus a need for effective systems of regulation and oversight. For these reasons, all industrialised countries have taken an active role in the organisation of health care. Even the USA, which stands apart from every other industrialised country in its misguided belief in the applicability of the market in health care, has established a substantial public sector, covering about 40% of the population to address at least some of the more obvious symptoms of market failure. As a consequence, Member States have explicitly stated, in the Treaties, that the organisation and delivery of health services and medical care remains a matter of national competence.

Nevertheless, many individual elements of health care are, entirely reasonably, subject to market principles. With the exception of some vaccines and drugs with specialised applications related to national security, governments generally do not produce or distribute pharmaceuticals. Health facilities purchase equipment, whether clinical or otherwise, on the free market. Both medical equipment and technology are freely traded on the international market. Many health professionals are self-employed, engaging in contracts with health authorities or funds. Patients may obtain treatment outside the statutory health care system, either in their own country or abroad. All of these matters are entirely legitimate subjects for applications of the internal market; indeed the fundamental freedoms enshrined in the Treaty require that such transactions are transparent and non-discriminatory.

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

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

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

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

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

The jurisprudence of the ECJ has created important uncertainties. Given the centrality of Regulation 1408/71 in the free movement of patients, these decisions have robbed it of much of its certainty. Consequently it seems necessary to undertake a revision of the whole legal framework regulating access to health care across the European Union. Since the issue is now attracting much attention - especially in countries where patients are confronted with waiting lists and other difficulties with access, and key actors are experimenting with new ways of meeting patients expectations, including across borders, some guidance is needed.
In the same way, the growth of electronic commerce also creates challenges to health policy, as recognised by the Council of Ministers’ call for information technology to be implemented in the health sector in ways that promote social inclusion.

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

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

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

The application of competition law in health care is also problematic. While many of the transactions within statutory systems may be exempt on social grounds, health authorities must be aware of the possibility of removing this protection through deregulation and privatisation.

The pharmaceutical sector creates numerous difficulties as the international dimension is so much greater than for many of the other issues considered here and the challenge of balancing trade and health policy concerns is especially acute. One example is direct to consumer advertising where there is strong commercial pressure to permit it but sound health policy reasons to reject it. The EU institutions have created a framework in which the supply of medicines has been harmonised along common lines to the benefit of drug manufacturers (and intermediate suppliers who source their products -parallel imports- from different markets within the EU) even in the face of intellectual property rights. European law and policy has had much less direct impact on the demand side. Pricing and reimbursement controls as demand side management techniques are only marginally impacted by EU law - whether primary treaty rules or secondary harmonising legislation. Proxy-demand side controls on doctors’ prescribing, wholesalers and pharmacists margins are outside the remit of EU pharmaceutical policies. However, e-health and e-commerce could provide many possibilities to break down the traditional single gatekeeper model of access, allowing multiple entry points and the direct distribution of information to patients. Whether this will allow the Commission to influence proxy demand and demand more directly remains to be seen.
While it is unnecessary to go through all of the issues raised in previous chapters, it is apparent that there are many other areas in which health policy and the promotion of the single market can either conflict or, more often, create ambiguities.

Many of these challenges arise from the growing role of the ECJ. Its role is to interpret the application of EU law in specific circumstances but these interpretations then establish precedents that are applied in different circumstances. Alter points out that “if member states cannot sway the interpretation of the ECJ, they may still be able to change the European law itself. This would not necessarily be an affront to the ECJ, nor it would necessarily undermine the Court’s legitimacy. The political system is supposed to work by having legislators draft and change laws, and courts apply laws”. (421)

However, the reality of the joint-decision trap makes it extremely difficult to reverse the ECJ advances based directly on an EC Treaty. Though in theory it should have been easier to change regulations and directives because of the possibilities offered by qualified majority voting, (422) in practice few ECJ interpretations have provoked legislative action to reverse the thrust of the decision.

This is because “most ECJ’s decisions .... affect member states differently, so there is no coalition of support to change disputed legislation.... After enough time passes, and enough protests or attempts to challenge ECJ jurisprudence lead nowhere, political passivity sets in....Inertia undermines the political will to effect change, and passivity is taken as a sign of tacit support”. (Erreur ! Signet non défini.)

As Dehouse has emphasised, ‘the tendency toward juridification may help to weaken the legitimacy of the integration process as a whole. The European Union is already suffering from a form of ‘political deficit’ to the extent that such actors as the political parties, the trade unions or even the media, whose actions often act as a reference point for national voters, are generally weak at European level’. (423)

Dehouse argues that by camouflaging conflicts of interest and replacing partisan conflicts with supposedly neutral debates on the interpretation of law, it considerably weakens the political process and offers opportunities to opponents of integration to claim that citizen’s democracy is replaced by a form of ‘judicial democracy’. Nonetheless, Dehouse also points out that the same process may be seen in a more positive light because litigation at European level can enable European to protect their rights against decisions of national administrations. However, ‘ECJ rulings may easily be perceived as intrusions calling in question the choices and traditions of national communities’. (424)

So what is to be done? This review suggests that a European health policy would bring considerable benefits, by setting out more explicitly an agreed position among Member States on what they are seeking to achieve through their health care systems. The evidence reviewed in Chapter 1 suggests that there is likely to be sufficient agreement to reach a common position, at least at the level of principles, although this does not imply that there is not considerable room for reform. However difficulties may arise when attempting to develop more detailed policies, given the wide diversity of arrangements in place in Member States to deliver health care.

The challenge that the EU faces is that its secondary legislation, such as directives and regulations, and the Court’s interpretation of them, must be based on what is in the Treaties. However, as this report has shown, the social character of European health systems is not embedded in the Treaties. Consequently, if the European social model is not to be undermined inadvertently by the inappropriate application of EU law designed to meet needs in other sectors
or a piecemeal series of judgements on health care, it will be necessary to agree on a statement of fundamental principles of general interest that enshrine the goals of European health systems, that balance the internal market with social goals, and that can be incorporated in a future Treaty.

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

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

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