The Influence of European Law On National Health Policy

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THE INFLUENCE OF EUROPEAN LAW ON NATIONAL HEALTH POLICY

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Summary

Formally, the European Union has relatively little role in health and health care. This paper offers a guide to those responsible for developing and implementing health policy within the member states of the European Union. It first describes the legislative framework of the Union, the formal position of health and health care in European Union law, and the concept of subsidiarity. It continues by examining a series of areas in which provisions related to the 'four freedoms' of movement of goods, services, persons and capital have implications for health and health care, such as free movement of professionals, of patients, of health care providers, and of pharmaceuticals. It concludes by considering when a member state can block free movement and how health can get on to the policy agenda.

Résumé

L'Union Européenenne n'a explicitement qu'un faible role dans domaine de la santé et des services de santé. Cet article se presente comme un guide pour ceux responsables du développement et de l'implémentation des politiques sanitaires au sein des États Membres de l'Union Européenne. Le context legislatif de l'Union d'abord décrit ainsi que la place occupée par la santé et les services de santé dans la Loi de l'Union Europeene et le concept de subsidiarité. Sont ensuit examinés plusieurs domaines dans lesquels les provisions liées aux 'quatre libertés' de circulation des biens, des services, des individus et du capital, ont des implications (directes ou indirectes) pour la santé et les services de santé, tels que la liberté de mouvement des professionnels de santé, des patients, des pourvoyeurs de soins, et des produits pharmaceutiques. L'article conclue en considerant quand un État Membre peut bloquer la libre circulation et comment la santé peut apparaitre sur l'agenda politique.

Introduction

Those involved in the development of policies on health and health care in the countries of the European Union must work within the frameworks of both national and European law. Although the various European treaties say little specifically about health or health care, there are many examples of laws that can constrain proposed policies. For example, attempts by the British government to reduce health care costs through contracting for support services (by transferring National Health Service employees to private companies at lower salaries) have been constrained by European employment law and, specifically, that covering the transfer of undertakings (European Commission 1977a).

This article provides those involved in developing policies with a guide to the relevant provisions in European law. It cannot be comprehensive, as knowledge of whether European law will constrain a particular policy will depend on what the particular policy

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seeks to achieve. It does, however, cover the key areas that are likely to be important. These are the free movement of professionals, of patients, of services such as health insurance and providers of health care, and of pharmaceuticals. It also examines the extent to which member states can limit the movement of goods or services on health grounds. It concludes that the scope of European law with regard to health and health care is limited but it can be important in specific circumstances. Health policy-makers must be aware of how their actions might be affected. It begins with a brief overview of the legislative framework of the European Union.

The legislative framework in the European Union

At the outset it is necessary to describe the instruments of European Union law and the scope for member states to interpret them. These consist of treaties, regulations, directives, decisions, and opinions and recommendations.

The various treaties enacted by the member states, such as the Treaty of Rome and the European Treaty on Political Union (the Maastricht Treaty) have the force of law in all member states and an individual in a member state can seek redress in his or her national court to enforce that law.

The treaties give the European Union competence in certain areas, in which it may then enact regulations and directives. These are proposed by the Commission and agreed through a process involving consideration by the Council of Ministers and the European Parliament. In certain cases, legislation may also be proposed by the Council or the Parliament. In the case of regulations, once they have been adopted by the Council they too have the force of law in all member states. The European Court of Justice has ruled that both treaty provisions and regulations take precedence over any conflicting national legislation (European Court of Justice 1964, European Court of Justice 1978).

Although they emerge from the same process as regulations, directives are implemented differently from regulations. Directives are means of harmonizing national law and they contain objectives that each member state must seek to achieve through national legislation but with freedom to frame laws in a way that is most appropriate to their situation. There is a time limit within which the law must be enacted but, once it is, individuals have redress as with any other national law. If, for any reason, a member state has failed to bring a directive into law within the requisite period, an individual also has recourse in a national court to action against that member state, or any public authority within it. The spectrum of organizations encompassed by the definition 'public authority' is wide and includes all those empowered by the state to provide a public service and given special powers to do so (European Court of Justice 1990). If the provisions of the directive are sufficiently clear to be applied by the national court, it is bound to do so. In such a case, the directive may pass into national law on the basis of precedent in a partial form or in a form that differs from what would have resulted had it been enacted by the national legislature (ter Kuile *et al.* 1992). A less common component of European law is the decision which has the power of a regulation but which is binding only on those member states, individuals, or organizations at which it is directed. There are also opinions and recommendations, which may be adopted by the Council of Ministers but do not have the force of law.

While the treaties, regulations and directives provide the basis of community law, much of the detailed interpretation is based on case law arising from rulings of the European Court of Justice.

Health and health care in European Union Law

For most of its existence, the European Community or Union has had very little specific competence in health or health care. Where it has been mentioned at all it has largely been in the context of health and safety at work, as in the 1951 European Coal and Steel Treaty and the 1956 Euratom Treaty, both dealing solely with those industries and in Articles 117 and 118 of the 1957 Treaty of Rome, which extended these provisions to other industries. The Treaty of Rome, which established the European Economic Community, provides the legal basis for the common market, defined subsequently in the 1985 Single European Act as conferring the 'four freedoms': the free movement of goods, persons, services and capital. Health is mentioned in Article 36, which empowered member states to limit trade in goods where it could be justified on grounds of protection of human health and life (discussed later). Finally, the free movement of services, while not specifically mentioning health care, had implications for health professionals.

Health was again mentioned in the 1985 Single European Act which, in Article 100a(3)2, stated that when the Community takes harmonizing measures to create a single market, the Commission will take a high level of health protection as a basis for its proposals in the field of health, safety, environmental protection and consumer protection. Again, this provision was based firmly in the requirement to support the four freedoms.

Other events in 1985 illustrated how, despite the absence of any formal competence at that time in the field of public health, it is possible to interpret general treaty provisions in a way that enables public health policies to be implemented. A French memorandum advocating a co-ordinated programme against cancer was endorsed by the Italian presidency and rapidly developed into the Europe against Cancer programme, which was finally adopted in 1988 (European Commission 1988a) with an initial annual budget of 10 million ecus. The programme encompassed campaigns against tobacco, improvements in nutrition, protection against carcinogenic agents, promotion of screening policies, the provision of information to the public and professionals, and research. The justification for Community competence in this field was that the Community has 'as its task ... to promote throughout the Community a harmonious development of economic activities, a continuous and balanced expansion and *an accelerated raising of the standard of living*' (European Commission 1986a) (emphasis added).

In 1991, a similar programme, 'Europe against AIDS', was adopted, encompassing the provision of information and training, exchange of information on services, research, and measures to promote the safety of blood.

Subsequently attempts have been made to develop European Union programmes against other diseases, such as nutrition (European Commission 1990), cardiovascular disease (European Heart Network *et al.* 1994), and Alzheimer's disease, so far without success. Proposed programmes on road safety (European Commission 1993a) and drugs (European Commission 1994a) are still under consideration although several specific activities exist in both areas, such as the European Drug Prevention Week (European Commission 1992a) and the European Child Safety Campaign (European Commission 1987).

In 1991, the Maastricht Treaty introduced the concept of subsidiarity that has important implications for many areas of national policy, including those concerned with health and health care. Article 3B of the Treaty states that:

> The Community shall act within the limits of the powers conferred upon it by this Treaty and of the objectives assigned to it therein. In areas which do not fall within its exclusive competence, the Community shall take action, in accordance with the principle

> of subsidiarity, only if and 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 of effects of the proposed action, be better achieved by the Community. Any action by the Community shall not go beyond what is necessary to achieve the objectives of this treaty.

The interpretation of this principle has provoked considerable discussion and has been the subject of clarification at subsequent summits. At the 1992 Edinburgh summit a three-stage test for future legislation was announced. First, has the Community competence to act? Second, if it does have competence, is it impossible to achieve the desired objectives at national level? And third, if measures are not attainable at national level, what is the minimum Community intervention necessary? But even this clarification leaves room for interpretation and decisions will continue to be influenced by the pattern of national perspectives and the relative power of the key players involved. For example, some members of the European Parliament envisage a relatively broad definition of Community competence (Schleicher 1994, Watson 1994a), and the current British government espouses a very narrow one.

The Maastricht Treaty also gave the European Union, for the first time, competence in the field of public health. This is set out principally in Article 129 (Figure 1) although Article 3(o) of the Treaty also charges the Community with contributing to the attainment of a high level of health protection. In essence, Article 129 enables the European Union to take action to co-ordinate national policies on the prevention of major diseases, including drug dependence, as well as health information and education. The provisions of Article 129 lie within the remit of Directorate General (DG) V, Employment, Industrial Relations and Social Affairs. The Union's scope for action is closely circumscribed. It may only provide incentives for action or, through a qualified majority vote in the Council, adopt a recommendation proposed by the Commission. for the purposes of the present review it should be noted that Article 129 is worded in a way that focuses on the prevention of major diseases rather than the broader promotion of health and its implementation reflects this, even though some Commission officials have indicated their desire to shift policies towards the broader determinants of health (Watson 1994b). Furthermore, by specifically excluding the issuance of directives or regulations, the scope for changing national policies is extremely limited. This certainly is the interpretation placed on the Article by some commentators although there is also a contrary view, which notes that the term 'incentive measures' has not previously been defined. Although the principle of subsidiarity suggests that such measures should be non-binding, the instruction that members states should co-ordinate their policies and that the Commission may take 'any useful initiative' to achieve this leaves open the possibility that measures that are, in effect, binding could be adopted by a qualified majority in the Council of Ministers as, even if the term 'incentive measures' is interpreted as purely programmes designed to stimulate activity, if these are accompanied by funds, as is likely, then national policies will inevitably be influenced by decisions made at a European level, as new developments supported under such programmes will comply with common objectives.

A related part of the treaty, Article 129a, charges the Community with contributing to the attainment of a high level of consumer protection through specific action which supports and supplements the policy pursued by the member states to protect the health, safety and economic interests of consumers and to provide adequate information to consumers. Importantly, the Treaty did not alter the fact that the provision of health services would remain exclusively the responsibility of the member states themselves and not the European Union.

1 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 sources, 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.

2 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 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 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 harmonisation of the laws and regulations of the Member States;

* acting by a qualified majority on a proposal from the Commission, shall adopt recommendations.

Figure 1 Article 129 of the Treaty on European Union

The apparent limitations of Maastricht's provisions on public health may stem from the fact that Article 129 was the result of a compromise between those who did not want a specific community mandate in health and those who wanted it to go further. Some member states supported the inclusion of Article 129 as it would set the limits to any expansion of European Union public health activities beyond what had earlier taken place without a clear legal basis, such as the AIDS and cancer programmes. There is little doubt that some national health officials viewed this new legal basis for health policy as little more than a formalization of earlier arrangements.

Following the ratification of Maastricht, the European Union's competence in public health has been developed further in a resolution setting out a framework for future action (European Commission 1993b). This accepted the need for collaboration between member states and the Commission involving a mechanism for consultation but noted that 'public health policy as such, except in cases where the Treaties provide otherwise, is the responsibility of the Member States'. It also noted the importance of a long-term approach to public health issues and the need to collaborate with other international organizations. It set out certain criteria for Community action. These are that there is a significant health problem and appropriate preventive actions are possible; the aim of the activity cannot be sufficiently achieved by the member states acting alone; the activity supplements or promotes other Community policies such as the operation of the Single Market; and that the activity is consistent with those of other international organizations, such as the World Health Organization. The document went on to note the need for better data to inform priority-setting and listed criteria related to burden of disease that should be used in setting priorities, such as mortality, morbidity, years of life impaired and cost, although, despite each of these measures suggesting different priorities, it gave no indication as to how these might be reconciled. The concrete actions

proposed in the framework documents were limited to the establishment of a high-level committee of representatives of member states, the exchange of information through networks of institutions specializing in particular areas and the exchange of personnel, the establishment of mechanisms to ensure that health policy is taken into account in other European Union policies, and mechanisms improved co-operation with international organizations.

A further document proposes a five-year programme for action in the field of health promotion, information, education and training (European Commission 1994b). This emerged from lengthy negotiations between the key actors, leading to formal conciliation in December 1995. Much of the disagreement has centred n the size of the budget, with the parliament advocating 35 million ecus over five years but the Council arguing for 30 million ecus. It seems likely that the vast majority of the budget will be committed to either the existing Europe against AIDS and Europe against Cancer programmes as well as a new programme on Alzheimer's Disease. A final decision by the Council is expected later in 1996. The proposed programme on Alzheimer's Disease was included following pressure from a small group of Members of the European Parliament and has been criticized by the Commission, the Council and some public health organizations, largely because it is inappropriate as a major element on a programme directed at prevention.

The consequences of the major European Union treaties for health care can be judged from one of the relatively few examples of where it has been addressed. As noted above, the 1985 Single European Act required the Community to place a high priority on health protection. A 1992 Council recommendation (and thus only advisory) recommended that Member States should

> Organize the role of social protection in preventing illness and in treating and rehabilitating the persons concerned so as to meet the following objectives:
>
> (a) *under conditions determined by each Member State*, to ensure for all persons resident within the territory of the Member State access to necessary health care as well as to facilities seeking to prevent illness; [emphasis added]
>
> (b) to maintain and, where necessary, develop a high-quality health care system geared to the evolving needs of the population, and especially those arising from dependence of the elderly, to the development of pathologies and therapies and the need to step up prevention
>
> (European Commission 1992b)

Consequently, at present, the situation with regard to health care is that the European Union simply recommends that member states should provide it and the manner of doing so is a matter for them.

In the context of the present discussion of how European Union policy might constrain the domestic policy it is also important to mention the forthcoming 1996 Intergovernmental Conference (IGC), at which the Maastricht Treaty will be reviewed. It is not possible to predict whether changes will be made in Article 129. However, it appears unlikely that the public health competence will be discussed in any detail, if at all. This is largely because the object of the IGC is not to dissect individual policy areas but to concentrate on broader themes related to the future of European integration. With larger political concerns such as expansion of the Union to eastern and central Europe and the resulting institutional reforms, the very small competence in public health may simple tiptoe through the IGC unscathed. This is at least the hope of a broad section of the European public health community who fear that by 'rocking the boat' on this issue and calling for greater European Union powers in this area, it may have the contrary effect and arouse opposition from states such as Germany and the UK who have not been noted for their enthusiasm for a European Union health competence. In 1995 there were perhaps the first signs that

health could be one of the areas of European Union competence that might be repatriated to member states during the IGC. It was reported in February that year that during a private dinner the European Union Essen Summit, Jacques Delors identified health as an inappropriate area for EU activity. British ministers especially were said to be 'pleasantly surprised' at this development. Critics of the European Union public health competence may also find support from Denmark, and while Germany is understood to support the principle of European Union action in public health, it is keen to minimize the associated cost.

However, despite these early rumblings of discontent it is now generally believed that there will be no concerted attack on the principle of a European Union public health competence at the IGC. Indeed, most agreed that since the health competence has only been around since 1993, it is still too early to make concrete judgements about its future. This is a point emphasized by Padraig Flynn, the European Commissioner with responsibility for health, who has indicated that he feels that change would be premature as its implications are not yet fully understood (Belcher 1995a: 5). Those member states, such as the United Kingdom, that place a strong emphasis on subsidiarity, are unwilling to see any extension of its limited provisions. But there are also calls for it to be strengthened, emanating from some politicians (Veil 1995) and from the European Union Economic and Social Committee (European Commission 1994c).

One particular issue that has been raised is the need for minimum standards of health care throughout the European Union. While European Union citizens have the right to settle and establish in any member state, they are presently faced with extremely varied levels of health care throughout the Union. British MEP David Bowe has called for the harmonization of national laws and regulations to ensure minimum standards (Bowe 1995). However, it is far from clear how such objectives could actually be achieved given the wide disparities in health care systems between some northern and southern member states. Essentially it would imply a massive transfer of resources to harmonize the quality of health care, and this would be unacceptable to northern states such as Germany.

Another problem which may warrant attention at the IGC is arriving at a clear set of priorities for European Union action on public health with the limited funding available, rather than acting on suggestions as they come along on an ad hoc basis. This problem was emphasized at the end of last year when the European Parliament decided to allocate 5 million ecus from the health promotion budget to a single disease group – Alzheimer's Disease. As noted earlier, it falls outside the eight priority areas for future action that had been agreed by member states and European Union institutions following ratification of Maastricht; drug dependence, cancer, AIDS and other communicable diseases, health data/indicators and monitoring and surveillance of diseases, intentional and unintentional accidents and injuries, pollution-related diseases, and rare diseases. Moreover, Alzheimer's Disease appears to fit uneasily into Maastricht's model of public health policy which emphasizes prevention and health promotion rather than treatment and cure. Its causes are not yet known so there is not information that can be given on how to prevent it and it is very difficult to diagnose. However, the European Union has been able to carry out work on this disease in other areas such as the BIOMED research programme and through a specific budget line for helping the elderly and their carers.

The funding for health is very limited and until member states provide the necessary financial support, European health policy cannot hope to tackle all the health problems facing European Union citizens. It is generally agreed that effort must be directed at a few carefully chosen areas rather than spreading resources and effort superficially over a large area. The IGC could therefore provide a valid opportunity to define the priorities, and importantly, to clarify the criteria for identifying them.

The preceding paragraphs provide an overview of only those European laws relating specifically to health. In addition, however, the European Union has competence in many other areas that relate less directly to health and health care. These span a large number of directorates general (Table 1). They include DG III (covering food safety, standardization of pharmaceuticals and medical equipment), DG XII (covering biomedical research), and DG XV (covering free movement of professionals and protection of data). In addition, health features in several of the Union's external policies, such as the PHARE and TACIS programmes of aid to central and eastern Europe and the former Soviet Union, within DG I. As Article 129 requires that health protection be a constituent part of all European Union policies, DG V has established an Interservice Group to liaise across Directorates General. The first report on progress in this area has been criticized by public health commentators (Belcher 1995b) for relying on reports from the other Directorates General that, inevitably, sought to justify what they were doing even when, as in the case of tobacco subsidies, they are clearly inconsistent with public health. Despite the limitations of the Commission report, it has been welcomed by the Council, which have asked the Commission to ensure that they identify potential issues at an early stage and report on progress annually to the Council. The Council indicated that they should pay particular attention to:

economic policy, in particular, taxation
social policy, including questions of employment
free movement of goods and persons
agricultural and food policy
consumer protection
research and development
environment
transport

Unfortunately it did not provide additional resources to do so.

Health care

As noted above, under the principle of subsidiarity, the organization of health services is a matter for member states alone. Consequently, in theory, European Union policies should have no effect on them. In practice, the four freedoms may have an impact in several areas. Free movement of persons has implications for both health professionals and patients. Free movement of services has, potentially, implications for health insurance. And free movement of goods includes pharmaceuticals. Although these provisions are fairly marginal to the development of national health policies, they could, in theory, constrain certain actions. Consequently it is important that policy-makers are aware of them. The following paragraphs consider each of them in turn, in each case starting with an overview of relevant European Union law followed by an analysis of how they might affect national policies.

Free movement of professionals

The right of health professionals to practise in another country of the European Union was established in articles 49, 57 and 66 of the Treaty of Rome. Subsequently this has been operationalized in a series of directives that has been issued with respect to doctors, dentists, pharmacists, nurses and midwives. In essence, all of these directives abolish restrictions based on the national origin of qualifications and give suitably qualified staff the right to practise in any member state, following application to a designated responsible authority in that member state. Other health professionals for whom there are not regulatory bodies in all member states, such as physiotherapists, are covered by a general directive that provides for mutual recognition of qualifications but no automatic right to practise. These groups will be considered in turn. The underlying freedom of professionals to practise in

Table 1 Overview of the health-related projects of the EC and the responsible Directorates-General (as of December 1995)

Topics	*I*	*III*	*IV*	*V*	*VI*	*VIII*	*XI*	*XII*	*XIII*	*XV*	*XVI*	*XXII*	*XXIV*
Health care													
Systems	X					X			X				
Provision			X								X		
Private insurance			X							X			
Medical													
Ageing population				X				X	X				
Disabled				X		X		X	X	X	X		X
Pharmaceuticals	X	X	X	X		X		X	X	X			X
Biotechnology		X			X		X	X	X				
Nutrition/diet	X	X		X	X	X	X	X		X			X
Genetics		X						X					
Immunology				X				X					
AIDS	X			X		X		X			X		
Cancer		X		X	X	X		X	X				
Neuro-sciences								X	X				
Radiation protection				X			X	X	X				
Transplants		X		X				X	X				
Health and safety				X			X	X					
Tobacco				X	X			X					
Technical Infrastructure													
Medical informatics		X		X		X		X	X				
Biomedical technology		X		X		X		X	X	X	X		X
Standardization		X											
Education/public health													
Education/degrees				X		X		X	X	X	X	X	
Epidemiology				X	X	X	X	X	X		X		X
Health economics/systems research				X		X		X	X			X	
Social sciences				X	X		X	X		X			
Health promotion				X				X					
Drugs	X			X				X					

Note: Areas of responsibility of Directorates-General (DG): DG I: external relations, DG III: industrial affairs, DG IV: competition, DG V: social affairs, DG VI: agriculture, DG VIII: development, DG XI: environment, DG XII: research and development, DG XIII: Education, training, youth, DG XXIV: Consumer Policy Service.

Source: Davaki and Mossialos (1994) and authors' estimates.

another country also enables them to offer services to those in another country without actually establishing themselves in that country, although member states can constrain this by arguing that certain specialized services require particular controls (European Court of Justice 1974), such as requiring certain practitioners to live within a certain distance of a practice or hospital. Such controls must, however, apply equally to their own as to other nationals.

Free movement of doctors was first guaranteed by two directives in 1975 (European Commission 1975a, European Commission 1975b) setting out the requirements for basic medical training and specialist qualification. A doctor obtaining a specialist qualification in one member state could be recognized in any

other member state where that speciality was itself recognized. In some cases, such as surgery, this was not an obstacle as it was recognized from the outset in all member states. In contrast, it was problematic for specialities such as public health that was recognized only in the United Kingdom and Ireland, although subsequently also in France and Finland (McKee *et al.* 1992). The original directives were supplemented by a series of subsequent amendments (European Commission 1989a), largely involving extending the number of specialities recognized in each member state and, more recently, to include the newer member states and the wider European Economic Area. Mutual recognition of qualifications in general practice, which must include a two-year training period, was established in 1986 (European Commission 1986b). The various directives were consolidated in a 1993 directive designed to clarify the situation (European Commission 1993c). There is an important exception to the directives. Those European Union citizens who undertook their medical training outside the Union – such as many British doctors who trained in India or Pakistan, or Spanish and Portuguese doctors who trained in Latin America – are not covered, although there are many bilateral agreements falling outside the scope of European law.

Free movement of dentists was brought about by two 1978 directives (European Commission 1978a, 1978b). This specifies the duration of professional training and also empowers member states to restrict the activities that an incoming dentist can undertake, reflecting differences in the content of national training programmes.

Movement of pharmacists is governed by 1985 directives (European Commission 1985a, 1985b) which, as with doctors and dentists, specify the duration of basic training. Pharmacists do not, however, have an automatic right to establish a pharmacy in another member state as some countries control the distribution of pharmacies.

Free movement of nurses is covered by directives adopted in 1977 and subsequently amended (European Commission 1977b, 1977c). These set out a minimum duration of training and the skills that must be acquired. Midwives also have the right of free movement, arising from 1980 directives and later amendments (European Commission 1980a, 1980b) that define the scope of midwifery as well as minimum periods of training and the format and content of that training.

As noted above, other groups whose professions are regulated at national level have the right of free movement under a 1989 'general system' directive (European Commission 1989b). This directive is complicated by the different policies of member states to regulation of each profession. For example, chiropody is regulated in France but not in Finland. The directive only becomes relevant if someone seeks to practise their profession in another country in which it is regulated, when they must apply to the designated national authority in that country. That authority may recognize the qualification or require additional information on experience, a test, or a probationary period of supervised practice. In all cases the applicant has the right to redress in national courts.

Free movement in practice The preceding paragraphs set out the legal basis of free movement. The practice is, however, somewhat different. Movement between member states by all professional groups has been relatively small, with a few exceptions. Hurwitz (1990) has studied the case of doctors. In the ten years following introduction of the relevant directives, the number of doctors moving to another country represented only 0.21 per cent of the total work-force over the entire period although the trend has been upward and in 1986 had risen to 3.4 per cent. In most cases significant movements relate more to traditional patterns of migration, many of which predate the issuance of the directives. These include migration from Ireland to the United Kingdom, between Belgium and the Netherlands, and from neighbouring countries to Luxembourg.

For the purpose of the present review, the important question is whether this limited level of professional migration is likely to continue. This can be considered by examining the factors determining the volume of movement. These have been categorized as administrative or bureaucratic, which may encourage or discourage migration; structural or macroeconomic which create push/pull factors in both recipient and donor countries; and personal factors which influence the individual decision to move.

Administrative/bureaucratic factors Despite the directives permitting free movement, the administrative barriers remain considerable. It is often difficult to identify the responsible authorities. One must then comply with the specific requirements of the host country. For example, in Greece nurses must undergo medical examinations encompassing chest X-rays, psychiatric reports, drug testing and other specialized investigations, all of which are at the applicants' expense. In some countries and for some groups, such as nurses in France and Germany, regulatory bodies are decentralized and these local bodies may be less well acquainted with procedures for recognition of foreign qualifications. This has resulted in, for example, regional bodies in the south of France refusing to accept British qualifications.

In some cases there is outright discrimination. This is often difficult to prove in individual cases although there is strong circumstantial evidence from many countries that foreign graduates tend to be concentrated in the less attractive specialities. In some cases this may be because of perceptions that training programmes are not, contrary to the spirit of the directives, actually of the same standard. This has been argued with respect to the much longer and more practical media specialist training programmes in the United Kingdom than in, for example, Italy. Where it is especially blatant, legal action is possible, such as where the French authorities were forced to withdraw the argument that nursing posts in public hospitals were exempt from the directives as they were within the civil service (European Court of Justice 1986a).

Structural/macroeconomic factors At a global level it has been suggested that national economic performance is a major determinant of migration of health professionals, with poor countries losing people to wealthier ones (Mejia *et al.* 1979). There is remarkably little research on this issue within Europe. One exception is a study by Gray and Phillips (1993). This ranked countries in terms of a composite index of factors that might be expected to influence migration of nurses, including gross national product (GNP) per capita, nurse earnings (in purchasing power parity and relative to national earnings), dependency ratio, and ratio of predicted number of nurses (in terms of GNP) to actual numbers. The authors concluded that on this basis Greece, Italy, the Netherlands and Ireland would be expected to be net exporters while Denmark, the United Kingdom, Germany and Denmark would be net importers. Such an approach provides some insight but it is complicated by the opportunity for other forms of behaviour in response to economic signals. Especially in nursing, where in many countries there is a large pool of trained staff not currently in employment, there is considerable scope for changes in the level of participation in employment.

Personal factors Almost by definition, these factors are difficult to categorize, often relating to family ties and other personal relationships. But one personal factor does merit consideration. Ability to speak the language of the host country is an important factor even though it is only necessary to have a 'sufficient' knowledge of the host country's language and language tests are illegal as a barrier to free movement. Consequently, growth in migration is likely to continue to be concentrated between those countries with shared language, such as Belgium and either France or the Netherlands or, increasingly, as a result of the

growing number of people speaking English as a second language, to the United Kingdom or Ireland.

Implications for national health care policies

The legal framework at European level offers many opportunities for movement of health professionals that have not been fully realized. Countries have the opportunity to put in place policies that will attract professionals although this will be limited by the extent to which their language is spoken elsewhere. Consequently, countries where one of the more widely used languages is spoken, such as French, English and German, have a natural advantage. Increasingly, some countries are seeking to attract doctors from other countries, such as the United Kingdom where German and Dutch doctors are filling training posts previously occupied by doctors from the British Commonwealth. It is also possible to encourage a climate in which immigration is reduced, largely through ensuring that indigenous supplies are adequate. It is not possible to limit emigration.

Free movement of patients

In general, the majority of citizens of any European Union country are entitled to medical treatment in another country under certain circumstances. These are set out in two regulations first promulgated in 1971 and amended subsequently (European Commission 1992c). Specifically, those covered are employed and self-employed European Union nationals who are insured or covered in one of the member states, pensoners who are European Union nationals, and members of families of these groups, irrespective of nationality. Those exclued are students and disabled or unemployed persons who are not members of the family of someone who is insured and civil servants covered by a specific insurance scheme that is not open to the rest of the population. The nature of an indivdual's entitlement and the means by which they can obtain it are determined by the nature of their travel.

The E111 system provides temporary medical cover for those on short stays abroad, such as tourists and business people. It is limited to treatment that is 'immediately necessary' for illness or accident that has arisen in the country concerned. This constraint is less restrictive for pensioners and has been extended to include dialysis to provide freedom of movement to those receiving it for end-stage renal failure (European Commission 1984). Those working abroad are covered for twelve months (with a possible extension to 24 months) and students resident abroad are covered by a separate scheme (E109). Unemployed people going abroad to seek work are covered by another scheme (E119) as are those working in international transport (E110). In each case, the requisite form should be obtained in advance from the relevant authority in the country of origin. It does not cover costs of repatriation.

It is also possible to travel abroad for planned medical treatment in certain circumstances, in this case under the E112 scheme. The responsible authority in the country of residence must give permission in advance and can do so if the treatment is not available in that country. However, if the treatment is specified as an entitlement in national legislation but cannot be provided within an appropriate time, taking account of the state of health of the individual concerned then the authority is obliged to issue a E112 form. It is not clear how this might work in practice and a sickness fund would only be required to agree to extra-territorial treatment in a particular case if it had previously accepted it as a general right. Finally, the directives entitle cross-border workers to receive treatment in both their country of work and of residence, although their families are only entitled to treatment in their country of residence.

It is recognized that factors such as the extent of entitlement for certain services, such as dental treatment, and the scale of co-payment differ between countries. Under all of these

schemes the individual is entitled to the level of treatment provided in the country where treatment is obtained rather than where he or she is insured.

Implications for national health care policies

As the preceding paragraphs indicate, much of the legislation concerning free movement of patients relates to those who become ill while on temporary visits abroad. It is only the E112 scheme that permits patients to travel abroad for treatment and this is only in certain limited circumstances. In considering whether this could be a means of circumventing national policies on rationing care it is important to recall that the patient has no automatic right to travel abroad for treatment paid for by the national health system. Obviously, it is still possible for anyone to travel abroad for treatment if they pay for it themselves or if a private insurer is willing to do so. It is also possible for a health care financing body, such as a sickness fund, to contract with a provider in another country to provide designated packages of treatment, as in the case with some British health authorities purchasing non-urgent surgery in northern France and the agreement by which the Belgian health insurance scheme will pay for treatment of those living within 15 km of the national border in a foreign hospital that is no more than 25 km from the frontier.

As with the right of free movement of professionals, the scale of movement has been very small. There are some specific examples where a member state has opted not to provide a high-technology service, perhaps on grounds of cost or because the national population is insufficient to justify the size of facility required for optimal results. This was the case with Greek patients requiring bone marrow transplantations. In addition, there are many examples of small non-European Union countries who have established agreements with countries within the Union for such treatments, such as Malta and Iceland. Problems with data collection preclude calculation of the total volume of cross-border care in the European Union but an impression can be gained from one study that has examined in detail the movement of patients across the frontiers between the Netherlands, Belgium and German (Starmans and Leidl 1994). Even in this region, where distances are relatively short and there are common languages, the volume of cross-border treatment was very low, constituting 2 per cent of patients at most and even then many patients who line in one of the other countries are working in the country where they are treated and thus also insured there. The authors note that the relatively high transaction costs involved are likely to remain a barrier to greater movement. Another study, by the Association Internationale de la Mutualité found that 90 per cent of movement under these provisions was between Belgium, France, Italy and Germany (Lewalle and Lona 1991).

Extra-territorial provision of health insurance

Although, in principle, the provisions of European law for a free market in services suggest a long-term objective of harmonization of social insurance, there is no specific provision as yet. Private health insurance is covered by some directives but these are limited to issues such as liquidity requirements and certain technical issues (European Commission 1972).

The rulings of the European Court on health insurance are very limited and it has stated that its rulings in the field of insurance cannot be applied to types other than those covered by the rulings because of the complexity involved. Nonetheless, the rulings in other fields may give some idea of the arguments that the Court might accept. The relevant principles are set out in Article 60 of the Treaty of Rome that permits regulation of professional services as long as it does not discriminate on grounds of nationality, it serves the public interest, and it is proportionate. Two considerations apply.

The first is establishment, or the state within which the company is situated. The second is authorization, or the ability to regulate it in the same way as would be the case with a national company. In the first case, a 'requirement of residence in the territory of the State where the service is provided can only be applied as an exception where the Member State is unable to apply other, less restrictive, measures to ensure respect for those rules' (European Court of Justice 1975). Where the provider has a place of business in a state, that state will normally have the ability to supervise it so a residence requirement would be unlawful. Concerning the second condition, establishment, if a company is subject to adequate supervision in the home state, further supervision is an unnecessary control (European Court of Justice 1981a). Perhaps the most relevant and comprehensive ruling was a case concerning the regulation of the German insurance industry that held that national governments were entitled to impose regulations for the public good and to use them to authorize services provided on their territory (European Court of Justice 1986b) although such regulation is subject to the proportionality test (see later).

A related issue relates to the principle of solidarity. It might be thought, under the principle of free movement of services, that an individual could seek to opt out of a social insurance fund to seek cover elsewhere, at lower cost. This view has been rejected by the Court which argued that public bodies, such as sickness funds carrying out public duties under the social security fund, exercise exclusively a social function and may, in some circumstances, not to be considered undertakings for the purposes of the Treaty (European Court of Justice 1993a). To be considered as such they must meet four criteria. First, they should serve a social purpose and have no profit motive. Second, they should be based on the principle of solidarity. Third, they should act within a statutory framework. Finally, they should not be able independently to determine their levels of contributions. A caveat is required. While these circumstances pertained in France, where the case arose, they may not be the case elsewhere and, if a country chose to open up the market to competing insurance companies, while it would still be able to impose regulations, it could not limit market entry on the basis of nationality.

Implications for national health care policies

These rulings suggest that the Court is likely to take the view that a social insurance organization could offer services in another state and need not become established in it. It would, however, be subject to national regulation providing this was not discriminatory. The principle of solidarity appears to be respected by the Court.

Further changes could, in theory, take two forms. One would draw on the experience of the Canadian system where a national system regulates a range of somewhat diverse provincial schemes. It is difficult to reconcile such a system with the principle of subsidiarity. A second possibility is that a competitive market in social insurance, with sicknesses funds in one country expanding into others. As noted above, the extent to which this might happen will be determined, in part, by the extent to which a country establishes the conditions for it to do so. Such a system is, in essence, an international extension of the abandoned Dekker reforms in the Netherlands or the recently reformed German system. Such a proposal faces two important obstacles. The first is political. It is likely that many national governments would view it as a threat to cost containment strategies or solidarity. The precise effects would be difficult to predict and would depend on the marketing and costing policies adopted by the incoming schemes. The second is technical. Such a system requires that there can be adjustment between funds to compensate for differences in risk. In theory, this may be possible but, in practice, the experience in the Netherlands (van den Ven *et al.* 1994) and with the analogous fundholding general practice in the United Kingdom (Sheldon *et al.* 1994) has suggested that it is, at the very least,

extremely difficult and, arguably, actually impossible.

A related possibility is pressure from commercial insurance companies, and especially those based in the United States, to penetrate European markets. There has been some limited movement by for profit chains into the United Kingdom private sector market. The extent to which they would seek to enter the social insurance market must remain speculative at present but there are some reasons to believe that this may not be a significant problem (Altenstetter 1992). The main one is that at the levels of health expenditure in Europe it will be difficult for them to obtain the levels of profits that they are getting in the United States, as long as national governments maintain the principle of solidarity and ensure that systems are not put in place that facilitate cream-skimming and other forms of market segmentation (Light 1995). As noted above, it is probably naive to believe that this can be done in a competitive market simply by risk compensation. Under European Union law there seems to be no obstacle to putting safeguards in place as long as they can be shown not to discriminate on national grounds or, if they do, the effect is proportionate to the social objectives pursued. Finally, the financial barriers to market entry are likely to remain high.

Free movement of health care providers

Article 59 of the Treaty of Rome requires that the provision of services must not be restricted except to the extent permitted under the treaty. It is necessary to consider how this might apply to organizations providing health services. This has been examined in detail by Cohen (1994) with particular regard to the implications for what is called the 'internal market' in the British National Health Service. The article will only apply where a service is transnational. This is defined as involving the provider moving to another member state to conduct the activity in question on a temporary basis, the provider and recipient of services remaining in separate member states and communicating by telephone, post or some other way, or the recipient moving to another member state to receive a service (Hartley *et al.* 1991). The next issue is whether health services are 'services' under the treaty. Health services provided privately have been held to be services (European Court of Justice 1984a) and this view was supported in a ruling that the Irish government was not permitted to suppress information on abortion services (European Court of Justice 1991). These cases do not, however, relate to services provided within the framework of a national health system. There is no case relating specifically to health services but some guidance is available from other sectors. The Court has held that education services provided as part of a national system are not services within the meaning of the Treaty (European Court of Justice 1988). A major factor in this ruling was that a service is held normally to be provided for remuneration. It was held that this is not the case where the recipient of the service receives it without charge, pays for it with a grant from the state, or, if she pays for it she is later reimbursed by the state. This view has been upheld in a subsequent judgment (European Court of Justice 1993b).

The legal situation is thus somewhat complicated and several issues remain unresolved. This can be illustrated by the hypothetical example of a for profit health care provider based in another member state arguing that it has the right to provide services and be paid within a national health insurance system. As such an organization would presumably also be selling its services to private insurers or citizens, it would be deemed to be a service and thus fall within the provision of Article 59. For contracts with social insurance funds, the health care provided seems likely to fall outside the Article on the test of remuneration. However, if a government has introduced a system of health insurance based on competing insurance companies, some of which may

be 'for profit', then the health care seems likely to fall in a grey area. In other words, there is no necessity for the provision of health care to fall within the Treaty but the country in question may configure its health care system in such a way as to create a market that would have this effect. Even if it were to do so, however, it would still be possible to impose rules relating to the type o providers with whom the system entered into contracts, providing these are transparent and not discriminatory on grounds of nationality.

The market for pharmaceuticals

At present there is no single market in pharmaceuticals as many aspects of pricing and availability are controlled by national governments as part of cost containment strategies. These include setting prices for products or, in the case of the United Kingdom, agreeing profit levels with industry. Under a 1989 directive, the process of setting prices must be transparent so that domestic products are not unfairly advantaged (European Commission 1989c).

In the absence of a single market, individuals may not always be able to get medicines they are taking in their home country when abroad. Furthermore, a drug that is available in one country without a doctor's prescription may require one elsewhere, it may be marketed under a different name, and its cost may vary up to tenfold. The Council has recently asked the Commission to determine the extent to which problems arise when a doctor in one country issues a prescription that is presented to a pharmacy in another country.

As the rules governing doctors' activities had been harmonized, the fact that a prescribing doctor was a foreign national or lived in another EC member state should not be taken as grounds for prohibiting or refusing to honour a prescription. This was the view of Commissioner Martin Bangemann who, in a written answer to a parliamentary question, argued that a prescription issued by a doctor from another member state provides the same guarantees for a patient as a prescription issued by a doctor registered in the country of issue. But a spokeswoman for the British General Medical Council argued that prescriptions were only valid in the UK if they were written by doctors registered with the General Medical Council (Anonymous 1993). This issue is not yet adequately resolved.

There are, however, many areas in which legislation has been harmonized. All medicines sold within the Union must meet agreed standards of safety and efficacy (European Commission 1965). Advertising of prescription drugs to the public is prohibited (European Commission 1992d) and advertisements for non-prescription drugs are regulated in that, for example, they must not be directed at children and must not guarantee particular effects. Information on packaging and leaflets is also specified and must include information on recommended dose, frequency of use, ingredients, potential side-effects, and name and address of the manufacturer (European Commission 1992e). Under the Product Liability Directive (European Commission 1985c), patients have a right to compensation for defective medicines although the directive allows a 'development risk defence' if it can be shown that, at the time of manufacture, the risk could not have been foreseen.

In addition, a new European Union-wide medicines licensing system has been implemented. A new institution, the European Medicines Evaluation Agency, based in London, will play an important role. All human and veterinary medicines can be dealt with in one of three ways. A company may apply to the Agency for a product licence valid in all member states. This is compulsory for products derived from biotechnology but optional for others. They may also apply to a national agency, in which case it must be accepted by all other member states through a process of mutual recognition in which objections may be lodged by any state for con-

sideration by the Committee of Proprietary Medicinal Products, with representatives from each member state. Finally, it remains possible for a company to apply for a licence in only one country, in which case existing national arrangements apply.

The new system will only authorize products which constitute significant innovations, or which are presented for an entirely new indication which is of significant therapeutic interest, or which employ processes which demonstrate significant therapeutic interest. The Commission and the Agency have not yet established criteria to define what is an innovative product. In addition, the workload of the Agency is not expected to be significant (approximately 40 to 60 market authorizations per year when the agency will be fully developed). This was the result of a compromise by the Commission to permit member states indirectly to exercise industrial policy through market authorization procedures, which are often linked with pricing decisions.

The question arises as to whether the law on free movement of goods precludes a national health system from restricting what it will purchase or reimburse. This was examined in a challenge to the imposition of a restricted list of pharmaceuticals in the Netherlands. The Court held that such a restricted list was justified as the Treaty did not prevent member states from protecting the financial basis of their national health systems as long as they did it in a way that did not discriminate on the basis of the country of origin of the product (European Court of Justice 1984b).

In the related field of medical technology, there are a series of directives covering largely technical issues. These have been reviewed in detail by Altenstetter who concludes that the consequences of these policies for national health systems are unpredictable but there is no evidence so far that they have been of major importance in terms of patterns of care (Altenstetter 1996).

The implications for national health care policy The number of pharmaceutical products marketed in different countries varies widely, from 2,200 in the Netherlands to 8,862 in Germany (1992), and is largely determined by decisions by health services and insurance funds about what will be covered. Increasingly, these bodies are introducing criteria of effectiveness or cost-effectiveness into their decisions and, in some cases, as with beta-interferon in the United Kingdom, there are proposals that new treatments should only be made available within the context of clinical trials. The existence of customs union makes it possible for someone to import medicines not available in their own country but they have no right under European Union law to require their insurer to pay for it. In essence, this is no different from the general right to travel abroad for treatment if someone pays for it personally.

The pharmaceutical industry argues that the existence of restrictions on what national health systems willl pay for and how much they will pay is a barrier to the free movement of goods, and it is likely to continue to press for these restrictions to be outlawed by European law. A common argument is that the low prices obtained in some countries, such as France and Spain, are insufficient to support research and thus global competitiveness (Matthews 1992), even though the industry frequently spends larger sums on promotion and advertising (Haaijer-Ruskamp and Dukes 1991). Conversely, national governments are likely to view restrictions as an effective means of cost containment and will seek to retain them. Opinions vary within the Commission (Chambers and Belcher 1994). It is possible that the public health component of the Maastricht Treaty may have introduced an unforeseen element into this issue. Pharmaceutical policy is based in DG III, responsible for Industrial Affairs. Until Maastricht, the European Union could only legitimately consider issues of competition, market share and the like. By stating that health protection should be a part of other policies it is possible to argue that the impact of costs on health budgets and individual af-

fordability is a legitimate concern. This is a view taken by, for example, the Parliamentary Committee on Heath, Environment and Consumer Protection. If this continues, with the support of DGV, the Commission may become less exclusively aligned with the interests of the pharmaceutical industry.

The impact of European Union policies on national health policies

The preceding sections indicate that the scope for positive direct European Union action to promote health is heavily circumscribed. In contrast, it is possible to identify many areas in which the market-oriented four freedoms may lead to policies that undermine national policies that seek to improve health and, in particular, impairs the freedom of national governments to restrict free movement of goods and individuals in the name of health promotion. In general, even where national policy or other public health concerns are an issue, a presumption of the need to promote free movement remains, based on its centrality to the Treaty of Rome. The European Court of Justice has ruled that a public policy argument must show that European Union policies threaten 'one of the fundamental interests of society' (European Court of Justice 1977).

When can a member state block free movement? As noted earlier, there is limited scope for national governments to restrict international movement of individuals and goods on grounds of public health. In the case of individuals, the power to refuse entry to a European Union citizen on grounds of public health was defined narrowly in 1964 (European Commission 1964) as the power to refuse entry or that issue of the first residence permit in that state and it can only be invoked if the individual suffers from certain designated contagious diseases. It cannot be sued to expel anyone already in the country.

The ability to restrict movements of goods is more complex and is based on an evolving body of law. The right to do so on grounds of a threat to public health was established in Article 36 of the Treaty of Rome, which also permitted restrictions on free movement on grounds of public security and morality. Thus, the British government has been permitted to ban the import of certain forms of pornography. However, in general, this provision is interpreted extremely strictly. The landmark ruling, the so-called *Cassis de Dijon* case, was where public health arguments were used unsuccessfully to oppose the import of a low alcohol liquor into Germany. The court ruled that a product lawfully marketed and produced in another member state must, in principle, be allowed into another member state (European Court of Justice 1979). It also established the test of proportionality, in that a policy requiring derogation under Article 36 must be proportionate to the objective being pursued and could not equally be achieved in another way not requiring derogation, such as enhanced labelling. Furthermore, a national measure to protect heath must constitute a 'seriously considered health policy' and the member state must show that the measure is both necessary to protect health and goes no further than is necessary (European Court of Justice 1982a).

National policies implemented on grounds of public health may be challenged if it can be shown that they have an indirect consequence in free movement of goods. This argument was used in a challenge to the Belgian government's policy of allowing certain premises to sell beer but not spirits. It was argued that this indirectly discriminated against foreign producers, who were the main manufacturers of spirits. The Belgian government argued that their policy was designed to reduce alcoholism. The Court decided that the policy was primarily concerned with domestic pubic health considerations and had only an indirect effect on trade (European Court of Justice 1982b). Consequently it was deemed to be legal.

In summary, a policy involving trade in goods may fall into one of three categories

(Shaw 1993). First, it may be clearly linked to community trade, in which case it will be allowed only rarely. Second, it may have no impact on community trade, in which case it does not fall within the scope of European Union law. Third, it may have some impact on community trade in which case the test of proportionality should be applied.

There have been concerns that the Treaty of Rome will drive health protection down to the lowest common denominator. The various European Union product safety provisions, in theory, should ensure that all products marketed are safe under normal conditions of use, either by virtue of the general product safety directive (European Commission 1992f) or one of the specific directives, such as those covering toys (European Commission 1988b) or electrical appliances (European Commission 1973). In practice, consumer organizations have expressed some concern about the effectiveness of some of the measures taken under these directives, such as the CE mark of conformity on toys (Consumers in Europe 1994).

The Court seems extremely vigilant to situations where public health arguments are being used to justify constraints on trade. For example, it rejected a British ban on poultry imports before Christmas 1981 that was ostensibly due to fears about importing Newcastle Disease but was viewed by many as an attempt to block imports of French turkeys (European Court of Justice 1982c). But the Court does seem willing to accept that it is acceptable to ban a product available in another country if it can be shown that there is a genuine doubt about its safety. This was set out in a ruling in a case in which the Dutch government banned nisin, a chemical in processed cheese, about which the evidence was equivocal and interpreted differently in different member states (European Court of Justice 1981b). Although not tested by the Court, it also seems that this provision may be used to ban movement of goods from one country to others outside the European Union. All exports of British beef, worldwide, were banned in response to the evidence that human cases of Creutzfeldt-Jakob disease may have been caused by bovine spongiform encephalopathy in British beef and widespread concern about the enforcement of public health regulations in the British meat industry (McKee *et al.* 1996). At the time of writing, the issue of banning in trade with third countries is still under consideration by the Court and, although the final outcome is not yet known, it has refused the request of the British government for an interim lifting of the ban, citing concerns about public health.

Getting health on the policy agenda

Health does not appear to occupy the political high ground at European (or frequently national) level. This is reflected in the fact that DGV of the European Commission (Social Affairs and Health) is generally considered to be one of the weakest and most junior Directorates-General alongside the power houses of agriculture and industry.

In theory the requirement in the Maastricht Treaty that health issues should be taken into account in all European Union policies should enable member states to argue in the Council of Ministers for certain policies to be adopted in a way that is congruent with public health objectives. However, such an interpretation would be somewhat naive and ignores the power of many vested interests, such as the tobacco and alcohol industries, on policy-making. Indeed, the Commission has accepted that 'health interests have to be carefully balanced with other interests such as economic and social factors' (European Commission 1995). In some cases concerns about health have been addressed simply because, had they not been, they would have acted as a barrier to trade, with member states possibly using health arguments to block import of foreign products. One example is an agreement to harmonize labelling of tobacco products which specified

the wording and format of health warnings (European Commission 1992g). However health warnings are only marginally effective in reducing tobacco consumption and elicit only moderate opposition from the tobacco industry (Stanley 1993). In contrast, it has still not been possible to agree on the much more effective policy of banning advertising, which is strongly opposed by the industry. The somewhat tortuous means by which European Union policies are developed gives ample scope for input by vested interests. For example, the British Department of Health has consistently voted against the proposed ban on tobacco advertising, rejecting the arguments of its chief economic advisor who has published a report showing that such a move would be effective in reducing smoking (UK Department of Health 1992). Several commentators have noted the coincidental generous political funding provided to the ruling British party by the tobacco industry (McKee and Lang 1996).

It is not possible to produce a comprehensive list of policies that conflict with national health objectives, partly because any list will immediately be obsolete. They include the effects of the dismantling or border controls where price differentials persist, failure to enact safety and social protection policies on grounds of competitiveness, and distortion of food prices by the Common Agricultural Policy. The following examples illustrate some of these.

Fiscal policy is an important means of reducing alcohol and tobacco consumption and is used explicitly in some member states such as France and the United Kingdom. However, the tax imposed varies very widely, from 16.6 ecus per 1,000 cigarettes in Spain to 146.6 ecus per 1,000 in Germany (1992 data) (Abel-Smith *et al.* 1995) and, in some member states, such as Denmark, tobacco prices have failed to increase in line with general inflation. The further relaxation of border controls following the Maastricht Treaty has led to a dramatic increase in smuggling across some frontiers, such as between the United Kingdom and France. This reduces the effectiveness of national policies based on pricing.

Attempts to improve safety standards on vehicles built within the European Union have been resisted by car manufacturers (Belcher 1995c). The need for competitiveness is also argued, unjustifiably in the eyes of many British commentators (Hutton 1995, McKee 1995), for the British opt-out from the Maastricht Treaty's social chapter.

The Common Agricultural Policy has been much criticized for promoting consumption of foods so as to tackle surpluses even when this conflicts with health considerations. Examples include the promotion of butter and beef but not fruit, vegetables, and pasta. Rayner has reviewed several of the more bizarre consequences of this policy (Rayner 1995). One was the case of European Union funding for a series of advertisements in the United Kingdom to promote butter that were later ruled by the Advertising Standards Authority to be misleading. Another is the promotion of whole but not skimmed or semi-skimmed milk. Perhaps the best known example, which continues to be an embarrassment to many Commission officials, is the policy of subsiding tobacco production, involving resources that far exceed European Union spending on cancer.

There is, however, one other way in which the European Union can have an important impact on health policy, albeit somewhat indirectly. Within the European Union there are large differences in many policies that affect health, such as transport, education, taxation, and social protection. There are also large inter-country differences in the pattern of diseases and the rate at which they are changing (Schaapveld *et al.* 1995). Increasingly, public health professionals and those in non-governmental organizations are looking to the experience of others. Examples include the much higher rates of teenage pregnancy and child traffic accidents in the United Kingdom than in the Netherlands or the much lower rate of increase in cases of AIDS in the United Kingdom than in France. The many programmes sup-

porting international collaboration in training and research, ranging from the large formal programmes such as ERASMUS and BIOMED to Commission funding for conferences, provide many opportunities for exchanging experience and information.

Conclusions

It is convenient to consider separately the potential impact of European Union policies on health and on health care. In the former case, the scope for direct and positive action designed specifically to improve health is relatively limited, partly because it is precluded from actions other than encouragement and the provisions of incentives; and partly because of the limited budget available for action. There is, however, considerable scope for indirect action by promoting exchanges of information and personnel, thus encouraging the diffusion of existing good practice throughout the Union.

In addition, however, there is considerable scope for the Union to develop policies in other areas with either beneficial or adverse consequences for health. Although obliged to take the implications for health into account when developing these policies, it is clear that other, conflicting interests often prevail and national health ministries, which are traditionally weaker than other ministries such as finance and industry, may be unable to argue effectively against them. Furthermore, the ability of a health ministry to advocate healthy public policies may be constrained by electoral considerations, such as the need to retain the support of coalition partners. However, the requirement in the Maastricht Treaty that health considerations should be incorporated in other policies provides the justification for DG V and the Parliament to intervene. Unfortunately, at least in the case of DG V, as noted above, the results so far have been disappointing.

In the field of health care, again, the scope for European Union action is highly constrained. Even where action has been taken to promote, for example, free movement of professionals, the impact has been very limited. There is still little movement of patients even across borders where other obstacles are minimal; and there seems little demand at present from either governments or sickness funds to develop a free movement in social insurance, although, in the latter case, moves to create a more competitive market in some countries could change this. If this does occur, however, it may be necessary for a directive on health insurance to be developed. Given the deference of the Court in previous cases to the principle of solidarity and cost containment, and consistent with the principle of subsidiarity, it seems likely that the impact of European Union law would be to reflect the present situation in most member states. A further consideration is that, even within a country, there are serious technical obstacles to introducing such a market.

This review is, inevitably, based on the current situation. The development of European Union policy is dynamic and reflects the evolving relationship between the key players involved: the Commission, the Council of Ministers, and the European Parliament. The rotating presidency of the Council gives countries an opportunity to introduce policies that are subsequently adopted, as was the case with, for example, Europe against Cancer. And, even with qualified majority voting, a small number of member states can block legislation for many years, as shown by the history of moves for a ban on tobacco advertising. All of these could change in the next few years, with the relationship between the various actors being reviewed at the forthcoming Intergovernmental Conference and several national governments facing elections. Furthermore the Intergovernmental Conference will consider amendments to the Maastricht Treaty and there have been calls to extend the scope of Article 129, including one by the European Parliament's Health, Environment, and Consumer Protection

Committee. It has agreed a series of detailed amendments that is currently under consideration by the full parliament. Finally, if the Council of Ministers continues to meet in secret and if there is not greater transparency about the relationships of members of the European Parliament with lobbyists, there will always be a suspicion that policies with an impact on health can be manipulated by wealthy vested interests. Fortunately some of the new member states, most notably Sweden, seem determined to open up this process to greater public scrutiny. Non-governmental organizations promoting health play an important informal part in scrutinizing forthcoming legislation but they can never hope to have the same level of resources as, for example, the alcohol and tobacco industries.

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