Health in Europe 2

Health law and policy in the European Union

Scott L Greer, Tamara K Hervey, Johan P Mackenbach, Martin McKee

From its origins as six western European countries coming together to reduce trade barriers, the European Union (EU) has expanded, both geographically and in the scope of its actions, to become an important supranational body whose policies affect almost all aspects of the lives of its citizens. This influence extends to health and health services. The EU’s formal responsibilities in health and health services are limited in scope, but, it has substantial indirect influence on them. In this paper, we describe the institutions of the EU, its legislative process, and the nature of its grants, networks, and projects, which bring together people from across the continent to discuss almost any issue. That should not obscure the real sources of power in the EU. The EU makes law (panel 1). The EU’s law is binding and enforceable. At the heart of EU law is the creation of a single European market: EU law removes restrictions on the free flow of goods, services, capital, and people across borders within the EU, and ensures free competition within that market. The EU legislative process and the Court of Justice of the EU interact in this process. In doing so, they are faced with a potential conflict. The EU Treaty (the agreement between the Member States that establishes the EU) has a specific article (Article 168) dealing with public health but this article is tightly circumscribed. It requires that “a high level of human health protection” be ensured within all EU policies and activities but it also states the EU “shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care.” However, many things that affect health or are needed to deliver health care are

termed platforms or forums, which ensure that the Commission can receive inputs from a wide range of stakeholders (table).

The EU is probably best known among researchers for its grants, networks, and projects, which bring together people from across the continent to discuss almost any issue. That should not obscure the real sources of power in the EU. The EU makes law (panel 1). The EU’s law is binding and enforceable. At the heart of EU law is the creation of a single European market: EU law removes restrictions on the free flow of goods, services, capital, and people across borders within the EU, and ensures free competition within that market. The EU legislative process and the Court of Justice of the EU interact in this process. In doing so, they are faced with a potential conflict. The EU Treaty (the agreement between the Member States that establishes the EU) has a specific article (Article 168) dealing with public health but this article is tightly circumscribed. It requires that “a high level of human health protection” be ensured within all EU policies and activities but it also states the EU “shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care.” However, many things that affect health or are needed to deliver health care are

Key messages

- The law and policies of the European Union (EU) have a substantial influence on health and health systems
- The influence of EU law includes regulation of medical devices and medicines, recognition and content of professional qualifications, and many aspects of health-care delivery
- So-called softer EU programmes, such as research grants and international benchmarking, promote networking, comparison of systems, and shared expectations about what constitutes good health care
- The EU has a major role affecting population health through policies that affect the economy and through policies in areas such as food, tobacco, or alcohol but it has not always done everything that it could in these areas to promote health
subject to the EU’s policies on free movement. What this means for health, and any other part of the welfare state, is that the explicit Treaty articles authorising the EU to enact measures affecting health are only a subordinate element of EU health law and policy. The real question is: how and when do internal market and competition law affect health?

Although they share commitments to solidarity, within a broad European welfare state tradition (whether Beveridgian or Bismarckian in historical origin) the health systems of the Member States are very different from each other. These differences are sometimes forgotten in debates that pit the so-called European social model against EU law—whether the claim is that EU law is protecting the European social model, or undermining it. EU law has particularly important implications for the health systems that have embraced elements of liberalisation, privatisation, competition, and consumer choice in countries such as Germany, Hungary, the Netherlands and, now, to a much greater degree than before, England.

This paper can only begin to address some of the most important of the many aspects of health and health policy that are influenced by EU laws and policies. We begin by looking at free movement as it affects health systems, such as trade in pharmaceuticals and mobility of patients and health-care professionals. We then look at the EU’s support for health systems, such as funding of research and exchange of information. Finally, we examine policies that affect public health, such as those related to tobacco, nutrition, alcohol, and communicable disease.

EU health law

EU law can arise from two sources. The first is legislation (mainly Directives and Regulations) that are proposed by the Commission and agreed by the Council of the European Union and the European Parliament. However, a second source exists, the decisions of the Court of Justice of the European Union, which acts when the meaning or applicability of this legislation, or of the Treaties that set up the EU, are unclear or, as in several areas related to health services, the legislative bodies have failed to act. In these cases, the Court of Justice of the European Union interprets the Treaty provisions and existing relevant legislation, thus setting legal precedents. However, as the court’s decisions relate to specific cases, the wider applicability of its rulings can often be unclear. Moreover, as the relevant Treaty provisions are essentially deregulatory (they aim to create the single market by removing barriers to trade and outlawing anticompetitive behaviour), such court-made law can have unpredictable and undesirable effects on health systems and trade in goods potentially hazardous to health. This situation arises because the effect of such court-made law is to remove national regulations, so as to create an area for free trade and open competition. That position stands in stark contrast with European health-care systems, which are highly regulated, because most are not organised on the basis

<table>
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<th>Role</th>
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<tr>
<td>European Commission</td>
<td>Executive; initiates legislation. Organised into Directorates General (DG); DG SANCO (covers public health and consumer affairs); DG Internal Market and Competition; DG Research; DG Employment and Social Affairs; DG Information Society also important</td>
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<tr>
<td>European Council</td>
<td>Co-legislature (representatives of governments of Member States); responsible for overall policy direction</td>
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<td>European Parliament</td>
<td>Co-legislature (directly elected). Committees for Environment, Public Health and Food Safety; Employment and Social Affairs; Internal Market and Consumer Protection</td>
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<tr>
<td>Court of Justice of the EU</td>
<td>Adjudicates on legal disputes referred to it by national courts</td>
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**Table:** Main European Union bodies for health

EU=European Union. NGO=non-governmental organisation.
of markets, and even when they are, the markets are heavily constrained to ensure, for instance, health equity and protection of human rights. It also stands in contrast with European approaches to regulation of potentially hazardous products.

The EU’s responsibilities for free movement of goods mean that it has a dense regulatory structure for pharmaceuticals, medical equipment, and medical devices including legislation, decisions, and guidance dating back to the 1960s. The EU has used both regulation and competition law to pursue its aims of opening up markets for these products, while seeking to ensure safety for patients.21 No pharmaceuticals or medical devices can be sold anywhere in the EU without compliance with this law, although the processes involved differ for drugs and devices (panel 315–17). EU laws seek to balance innovation and safety in new health technologies, such as the products of biotechnology and nanotechnology. The EU treads a difficult line between supporting nationally based intellectual property rights, such as patents, that encourage medical innovation while seeking to have products traded on a single market. It is regularly criticised for stifling innovation by industry and for paying insufficient attention to the needs of patients. EU law gives favourable intellectual property rights and market authorisation procedures to orphan medicines and paediatric medicines. The EU has so far been unsuccessful in affecting national price controls for pharmaceuticals, although a proposal made in 2012 seeks to increase transparency.

Regulation is controversial. The European Medicines Agency, based in London, UK, has come under much scrutiny, with accusations that it places the interests of the pharmaceutical industry above those of the patient. A particular concern relates to its refusal to report the data on which it makes its decisions lest publication damages the commercial interests of the companies that provide information about their products. A particularly egregious example involved the almost 4 year struggle by the Nordic Cochrane Centre to obtain data for two drugs intended to assist weight loss.19 The agency repeatedly refused to release the data, despite demands to do so by the EU’s Ombudsman, who dismissed as spurious the bizarre succession of reasons invoked by the agency for withholding the data, even after one of the drugs was withdrawn on safety grounds.

The EU also regulates blood, organs, and human tissue. EU legislation concerned with quality and safety of such products requires Member States to set up risk assessment and monitoring institutions, and to collect and share information. The legislation also purports to encourage the so-called gift relationship model of blood, tissue, and organ donation, by exhorting Member States to seek non-market models, although such models are not made compulsory. In fact, a substantial market exists in blood and blood products within the EU.21

The EU’s responsibility for ensuring free movement of people means that it coordinates the social security entitlements of migrant labour through law originally adopted in the 1970s. This includes access for patients to EU health-care systems beyond the country in which they live. Most of this law is uncontroversial, because the home Member State authorises the terms on which migrant patients are entitled to receive benefits in a host country. But this system began to be questioned when the Court of Justice of the EU decided a high-profile series of cases beginning in the 1990s, involving patients using their rights to free movement of services in EU law to claim treatments in another Member State and be reimbursed by their home health system.22 EU

Panel 1: European Union law

The present powers of the European Union (EU) to legislate (legal competences) are set out in the Treaty on European Union and Treaty on the Functioning of the European Union. These treaties have been agreed by the Member States, and are the product of revisions over time to take account of changing circumstances and intentions of the Member States. Some treaty provisions give directly enforceable rights to individuals, such as the right to move freely to receive (medical) services in the EU. However, in general, to be of practical use, the treaty objectives must be converted into detailed EU law and transposed and implemented into the national laws of each Member State. There are two main means by which this can be done:

1 Regulations: these are used where a specific objective is to be achieved and no need (or desire) exists to adapt the legal wording to take account of national specificities, such as technical aspects of international trade. Regulations are binding in their entirety and directly applicable in all Member States, that is, they take effect without formally being written into national law.

2 Directives: these are the most common EU legislative mechanism. They are used when the objectives, which are binding, are agreed, but the means of achieving them must be decided by each Member State. The Member State must then transpose the directive into national law within a specified timetable. Sometimes a Member State simply copies over the text of the directive into national law. Other times a Member State rewrites the legal text to fit better with existing national law. Directives are binding, but take effect only on transposition, or after the deadline for transposition has elapsed.

EU law has supremacy over national law, to prevent selective adherence by Member States. All national courts, including constitutional courts, must apply EU law. Because of the complexity of the EU, the difficulty of agreeing legislation in a system with many veto points, and the impossibility of foreseeing every possible circumstance in which legislation might apply, much EU law has developed as a result of decisions by the Court of Justice of the European Union. Many important decisions interpret very general and apparently vague provisions in the treaties. This is especially true in relation to health services, for which EU institutions have been reluctant to legislate but for which many aspects are covered, in some way, by provisions on free movement of goods, services, establishments, and people, and free competition.

Some of these decisions have arisen as a result of legal action taken by individuals seeking to assert their rights arising from the direct effect of the treaties, which might arise when Member States (including a broadly defined group of public bodies acting on their behalf) have acted contrary to treaty provisions or when they have failed to legislate to give force to the provisions or have done so in a way that is unclear. To be termed directly effective, treaty provisions must be sufficiently clear and unconditional and there must be no scope for Member States to exercise discretion in implementation. All the key free movement and competition treaty provisions are directly effective.
Panel 2: European Union legislative process

Over time, there have been several variants of the European Union (EU) legislative process, but the main process now (the ordinary legislative procedure) essentially involves a proposal from the European Commission, and joint adoption by the European Parliament and Council. There are many veto points in the legislative process, making it very difficult to adopt EU legislation.

Phase 1: proposal
- Ordinarily issued by the Commission. The Commission usually consults with many stakeholders, often issuing Green or White Papers, or both, beforehand. However, the proposal can be from the European Parliament.
- Communicated to national parliaments, who can comment on whether the proposal ought properly to be dealt with at EU level, under the principle of subsidiarity.

Phase 2: first reading
- Parliament appoints a Rapporteur. Proposal is discussed in the relevant Parliamentary Committee.
- Proposed amendments are communicated to Council.
- Council adopts its amendments, acting by qualified majority (weighted voting according, put simply, to the size of the Member State).
- Proposed amendments are communicated to Commission, which adopts an opinion on them.

Phase 3: second reading
- Parliament considers Council amendments. If amendments are rejected by an absolute majority, that is the end of the proposal.
- Otherwise, Parliament proposes further amendments to the Council position.
- If Council does not agree, moves to the conciliation stage.
- Action within this phase is subject to time limits.

Phase 4: conciliation
- A conciliation committee is formed, consisting of representatives of the Member States and an equal number of Members of the European Parliament, showing the political complexion of the European Parliament. The committee has 6 weeks to agree a joint text, which is then presented to Parliament and Council for approval. If the conciliation committee fails to come up with an agreed text, that is the end of the proposal.
- The joint text is approved by Parliament (by majority of votes cast) and Council (by qualified majority).

Source: European Parliament.13

legislature sought to stop this judicial lawmaking by adopting the Directive on Patients’ Rights in Cross-border Healthcare in 2011. This directive consolidates important principles of the court’s law, and takes some of them further, for instance making it clear that Member States need not reimburse treatment in another Member State where substantial medical infrastructure is used, or where the treatment could endanger the patient. But it leaves several important questions unanswered, not least what it means in practice for values such as solidarity and equality of access to health care.21

Similarly, professional mobility is a long-standing area of EU health policy.22 The medical and nursing professions were among the first to be regulated in this way (in the 1970s) by the EU. The basic logic of EU professional mobility law is mutual recognition of qualifications: the law sets a minimum standard (eg, for the number of hours and years of training a doctor must have) and then regards qualifications from different countries as equivalent; or law requires states to decide whether qualifications are equivalent, and if not, what compensating measures need to be taken so that a professional can work in another Member State. EU law allows scrutiny of practices that discriminate against professionals from other countries, an issue that has previously been a particular problem with regard to employment in the public service.23 It underpins high levels of workforce mobility that now present serious policy and management challenges for some exporting countries in eastern Europe (panel 414).24 The EU is currently in the process of revising its professional mobility law to liberalise it further across the EU, a matter of concern to many professional associations, which have expressed worries about how quality can be ensured. EU law also regulates working time, which has caused problems for hospitals in some countries such as the Netherlands and the UK.

Some Member States have been forced to modify aspects of their national health systems after successful litigation relying on EU internal market and competition law as it relates to free movement of people and services. Restrictive regulatory arrangements for hospitals, general practitioners, pharmacies, clinical laboratories, dental practices, and establishments handling blood and blood products have been tested in the courts and by national competition authorities for their compatibility with EU internal market and competition law.25 These include single-practice rules, prohibiting health professionals from being registered or practising in more than one Member State; territorial or capacity planning rules, restricting the numbers of health-care professionals operating in a geographical area, or the system as a whole; limitations on the choice of legal suppliers of long-term care from making profits (although in this specific case, the rule was held to be justified). Merely stating that a regulatory arrangement is part of the structure and ethos of the national health system is inadequate as a defence in these cases. Governments have to show that the reason for the policy (eg, safety of patients, timely access to care, professional ethics, financial stability of the system) justifies any constraint on the operation of the market.

EU support for health systems
The EU is not only a supranational regulatory (or deregulatory) apparatus. Its permeability to lobbying, its leaders’ desire for popularity, and the structural desire of
that fewer than half led to a publication.31 The EU also a systematic investigation of its funded projects showed lagging in the late 1990s, the Dutch reaction to high rates of HIV infection among homeless people.32–34 The intention is to gain the support or sustain human life, are of substantial importance in preventing impairment of human health, or which prevent a potential, unreasonable risk of illness or injury” are “safe and effective for its intended use”16 or where it is substantially equivalent to existing products. These procedural differences have led to several products being approved in Europe but not in the USA.17 including a lung sealant system that was subsequently recalled, a drug-eluting stent later withdrawn after being found to offer no clinical advantage, and most notoriously, the Poly Implant Prosthèse breast implants, later found to have an unexpectedly high rate of rupture, leading to major programmes in many countries to remove and replace them. The EU’s medical devices regulation is currently under review.

Reference networks
The EU has been gradually developing reference networks, for instance, for rare diseases (ie, those that occur in <5 per 10 000 people). The intention is to gain the benefits of specialisation and economies of scale. Although the prospect of using EU structures to help people who could not get treatment in their home country is exciting, there are major questions about this initiative, in terms of membership and coordination of networks, how rare diseases are defined, and, crucially, who will pay if a network refers a patient for an expensive treatment in another country.

Comparative data
Finally, the EU seeks to influence health policy through talk, comparison, and debate. The basic model involves agreement on broad objectives, such as high-quality health care, and development of indicators, followed by reporting by different states against these benchmarks, and finally formulation of general policy guidelines. In general, the Commission, both directly and through its many forums, platforms, High Level Groups, and data-gathering projects, can do two things. One is obvious: inspire Member States to do better by producing comparative data and empowering networks among their policy experts. A Member State that had been ignoring a problem might be shocked into action by discovering how it looks in comparative perspective, as with the English reaction to cancer statistics showing England lagging in the late 1990s, the Dutch reaction to high rates of perinatal mortality, and the French reaction to high rates of HIV infection among homeless people.32–34 The other is less obvious. EU institutions, along with the European Central Bank and International Monetary Fund, are currently imposing fiscal frameworks on the Eurozone Member States, and are particularly intrusive in the policy decisions of peripheral Eurozone states.35 The discourse in Brussels (Belgium), Frankfurt (Germany), and Washington, DC (USA) is focused on budget cuts rather than health but the consequences can be severe for health systems. In this way, although they are not the direct object of EU policies, health systems are the casualties of sometimes severe budgetary reductions,36 an issue that is explored in more detail in another paper in this series.37

Public health policies
The EU’s contributions to public health are mixed: it has done a lot of good in some areas but has neglected to do so in others. Because the EU regulates the single market, it cannot avoid having an effect on public health through its policies on the production and distribution of tobacco, food, alcohol, cars, or other consumer products affecting health. In some areas, such as road traffic safety and control of air pollution, the EU has played a part in effectively regulating health hazards to lower and lower levels, but in other areas the power of industry lobbies in the Commission, Parliament, and Member States has restrained the potentially vast power of the EU to only a few policy approaches. When little or no political and
European Union (EU) professional mobility law poses particular problems when healthcare professionals cross borders only to provide intermittent services, rather than to become permanently established. Many differences exist in contexts for professional practice in different Member States, and the tensions between a desire to provide continuity of care and the use of professional mobility to fill capacity gaps, raise serious concerns. The tragic 2010 Daniel Ubani case involved a German doctor who killed a patient (David Gray) through an overdose of diamorphine, on his first UK shift as a locum. Dr Ubani, who later said he was unfamiliar with the drug, had flown in from Germany the day before and had only a few hours of sleep. He was convicted of gross negligence and manslaughter, and struck off the UK register of general practitioners, though apparently continues to practise in his home state. David Gray’s sons are seeking to bring a claim to the European Court of Human Rights (not an EU body) because of the way that the British and German criminal justice systems dealt with the case. After the inquest into David Gray’s death, Coroner William Morris called for an urgent review of the way that the British and German criminal justice systems dealt with the case. After the inquest into David Gray’s death, Coroner William Morris called for an urgent review of European laws that allow doctors’ qualifications to be recognised officially across the EU. The British Medical Association, General Medical Council, and the House of Commons European laws that allow doctors’ qualifications to be recognised officially across the EU. The British Medical Association, General Medical Council, and the House of Commons European laws that allow doctors’ qualifications to be recognised officially across the EU. The British Medical Association, General Medical Council, and the House of Commons European laws that allow doctors’ qualifications to be recognised officially across the EU. The British Medical Association, General Medical Council, and the House of Commons European laws that allow doctors’ qualifications to be recognised officially across the EU. The British Medical Association, General Medical Council, and the House of Commons

Legal scope exists for powerful new law, the Commission invests in more talk to keep issues on the agenda and supports non-governmental organisations (NGOs) and advocates who will be there when the politics become more propitious. The result is that EU public health policies tend to combine actions industry can tolerate, a great deal of talk and capacity-building of NGOs, and the British Medical Association, General Medical Council, and the House of Commons Health Committee have called for stricter regulation of overseas medical professionals. Such regulation must comply with EU laws on free movement.

**Panel 4: The Ubani case**

**Tobacco**

The first real EU tobacco policy was the decision to subsidise its farmers under the Common Agricultural Policy, in 1970. In view of that starting point, the EU has made quite a contribution to public health. The first anti-tobacco campaign was announced in 1985, and since then EU policy makers have considered and taken many measures despite strong opposition from the tobacco industry (including the large industry producing equipment for tobacco manufacture, concentrated in Germany). Legally enforceable bans on smokeless tobacco, limits on toxic ingredients, and financing of capacity building for anti-tobacco NGOs, all policies from the 1990s, seem trivial next to the Tobacco Advertising Directive of 1997, which was an EU-wide ban on most forms of tobacco advertising. It came under immediate legal attack and was struck down by the Court of Justice of the EU in 2000. Anti-tobacco advocates regrouped and won several victories in 2003, including a revised ban on many forms of advertising that has been upheld in the courts, graphic warning labels, and signature of the Framework Convention on Tobacco Control. Germany had opposed most and watered down many of these actions, because of its combination of limited public health advocacy, strong tobacco-related industries, and widespread industry funding for purportedly independent scientists. In 2006, the Commission sued Germany for inaccurate transposition of the advertising ban. However, since that year, no such legislative achievements in reducing smoking have been made (though fire-safe cigarettes are now mandatory). Donley Studlar argues that this shows a shift from outright opposition to tobacco, to a harm-reduction approach that is politically less costly. The stability of any such policy is open to question, though, since the politically sophisticated tobacco industry is working hard to undermine anti-tobacco policy at the state, EU, and international levels. Mystery still envelops the role of the tobacco industry in events surrounding the dismissal, on grounds of alleged impropriety, of the EU Health Commissioner in October, 2012. This situation led to widespread concerns that there might be a delay in progress of a new Tobacco Products Directive but the new Commissioner seems to be moving it forward.

**Obesity**

The EU is a common market for food and food products, which has increased cross-boundary flows of both healthy and unhealthy foods, and which is ruled by regulations and subsidies set in Brussels that shape European and global diets. Whereas initially the need for security of food supplies after World War 2 in Europe, and the powerful farmers’ lobbies, shaped policy, policy shifted to take account of health when a standard requirement for nutrition labelling was adopted in 1979. Starting in the 1990s, an increase in obesity in traditionally thin countries such as France and Spain and the growth of a worldwide anti-obesity movement drew policy makers’ attention to the social changes leading to population-level weight gain. In principle, the EU has tremendously powerful instruments to address obesity: the Common Agricultural Policy above all, but also food regulation and even the ability to finance healthy infrastructure and education through its grant-making programmes. In practice, the politics of food and the broadly right-wing nature of EU governments in the past decade have sharply limited the scope of the public health agenda and EU policies. The most effective and tangible policy under discussion would be a revision of nutrition labelling standards.

Although the opening up of markets has made it easier for countries in northern Europe to import fresh fruits and vegetables from the south, the overall effect on dietary patterns has been mixed. The Common Agricultural Policy provides subsidies for many agricultural products but especially for those containing saturated fats and sugars, while artificially increasing prices of fresh fruit and vegetables. Several studies have concluded that these policies contribute substantially to the burden of cardiovascular disease in Europe. Although several reforms have been undertaken, concerns remain that agricultural policy takes primacy over health considerations. However, public health advocates calling for
further reforms should note that changing the Common Agricultural Policy might be politically dangerous because, with the present probusiness complexion of the EU, reform would provide as many openings for obesogenic as healthy policy changes.

After a long battle with industry, which used its ability to lobby in the Parliament especially effectively, the EU adopted legislation regulating health claims (so that a product can be called “healthy” if it has 30% less sugar, salt, and fat than similar products in its category). The European Food Safety Agency, charged with validating industry claims, was overwhelmed and subject to repeated political attack as it emerged that, despite this looser definition of healthy, it was still rejecting about 80% of claims. However, more recently the agency has been subject to serious criticism because of its failure to rigorously assess industry claims (panel 5[48]). Only in 2012, did the Court of Justice of the EU hold that EU law prohibits promotion of wine on the basis of health claims.56 In 2008, the Commission proposed the introduction of a revised legal standard for food labels, including easy to understand traffic-light symbols on all packaging (for fat, salt, sugar, and calorie content; green for low levels, yellow for medium levels, and red for high levels). Although the European Parliament weakened the law, it did eventually pass but without traffic lights and with greater freedom for producers to shrink font sizes and decide where to place labels.57,58 With its policy options still further limited by political realities, DG SANCO has resorted to talking and data comparison mechanisms. The centrepiece is a Platform on Diet, Nutrition, and Physical Activity: a forum that brings together governments, firms, and NGOs to discuss food policy objectives and make (unenforceable) commitments to act. Under Director-General for Health and Consumer Affairs Robert Madelin (2004–10), who took the platform seriously, it had good attendance and served the interests both of industry (which could use it to show corporate responsibility and fend off regulation) and of the NGO and scholarly community. It remains a low-profile forum through which some information flows.59

**Alcohol**

The diversity of European drinking patterns and alcohol policies long inhibited EU-level debate, let alone action. EU law has been used since the 1970s to promote free movement of alcohol within the EU, and public health arguments were given short shrift by the Court of Justice of the EU. Even when the Nordic states, with their distinctive alcohol-related public health discussions, joined the EU in 1995, most EU action was led by the Court of Justice of the EU, with successful legal challenges to public health measures, such as national alcohol monopolies and other restrictions on sales and advertising. Even evidence that alcohol-related diseases had increased substantially in Denmark (a Member State since 1973) made no difference to the Court of Justice of the EU’s indifference to public health arguments justifying restrictions on free movement or competition in the alcohol sector.59 EU policy makers first became concerned about alcohol when the late 1990s saw the diffusion of sweet alcohol drinks (alcopops) among young people, and the uptake of northern European drinking patterns in southern Europe.60 In 2001, the Council (led by Sweden and France) adopted a non-binding recommendation advocating policies to reduce youth drinking, and, in 2002, the EU put forth its first range of measures and suggestions, including a standard European blood alcohol concentration for drunk driving. EU measures since then have become more numerous and visible, and are focused in areas where political consensus exists and any damage to the industry’s profits is small: prevention of underage drinking, measures against drunk driving, a focus on reducing problem drinking and drinking among certain populations such as pregnant women, and, of course, research and education. These are all measures that the alcohol industry can countenance. More effective anti-alcohol measures such as taxation, minimum prices, and restrictions on advertising and service have so far met with effective political resistance from industry and some Member States that dislike EU infringement on sovereignty or social policy.61 This situation is reminiscent of the food policy area, and has many of the same actors. The industry has won many battles, but not all, and effort has focused in areas that industry will not oppose too strongly. Meanwhile, the Commission is trying to build capacity among advocates and NGOs, and keep debate alive through forums such as an Alcohol and Health Forum.

**Communicable diseases**

Common European policy on control of communicable diseases seems like a natural part of any common European market: if people, food, and animals are to cross borders, then so will bacteria and viruses. It would seem wise to develop the necessary epidemiological

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**Panel 5: The European Food Safety Agency and sports drinks**

The European Food Safety Agency (EFSA) has, like the European Medicines Agency, been criticised for the means by which it reaches its decisions. In the past year, controversy has centred on claims for the benefits of sports drinks, products promoted as improving performance of athletes by boosting hydration, despite the absence of evidence that they are effective in doing so.62 Yet the EFSA upheld the claims made by the companies, drawing on a review by an American body that had received a large donation from one of the manufacturers of sports drinks.63 By contrast, the US Institute of Medicine, after reviewing the same evidence, questioned the claims because of inadequacies in the database. A study undertaken to replicate the assessment made by the EFSA also questioned the quality of the evidence used and its interpretation and drew attention to serious weaknesses in the EFSA’s procedures, including dependence on manufacturers to supply evidence, with the inevitable risk of bias, and absence of explicit criteria to establish what evidence should be included and how it should be assessed.64
Organised networks of public health—such as research, rare diseases, centres of excellence, and public health programmes—are often the most visible to health professionals. But the real power in the EU lies in its law, and the law is sometimes deregulatory and disruptive rather than supportive. As a result, EU law has had both positive and negative effects on population health.

**Conclusions**

Observers often misjudge the effect of the EU on health policy or are poorly informed about it. Initiatives in areas such as research, rare diseases, centres of excellence, and public health programmes are often the most visible to health professionals. But the real power in the EU lies in its law, and the law is sometimes deregulatory and disruptive rather than supportive. As a result, EU law has had both positive and negative effects on population health.

Although European legislation can have a direct effect, usually it must first be transposed into national law and then implemented. This is not always a simple process. EU legislation sets out aspirations and requirements that are often distant from the real world. The act of transposition, whereby EU law is written into national law and policy, is an inexact process. Member States will often overshoot or undershoot, adding policies they wanted to make anyway or failing to comply. It takes time for such failures to be picked up by legal processes and

Road traffic and air pollution

Although the EU has not yet been very effective in reducing the health hazards related to tobacco, obesogenic food, alcohol, and infectious diseases, it has helped to improve road traffic safety and reduce air pollution. In 2001, the EU set itself a target of halving the yearly number of road deaths between 2001 and 2010, by stimulating member states to implement national road traffic safety programmes, by providing EU funding for improvement of road infrastructure, and by upregulation of vehicle safety standards. Partly as a result of this EU programme, road traffic deaths declined by 43% in the 27 Member States. Similarly, EU directives have set increasingly ambitious emission ceilings for air pollutants, both for motorised vehicles and for industries. These stimulated the implementation of technological improvements and have helped to substantially reduce the emission of sulphur dioxide, lead in petrol, particulate matter, and nitrogen oxides. EU air emission policies are estimated to have reduced the negative health effect of the road transport sector in Europe as a whole (measured in terms of years of life lost) by 30%, and that of the industrial sector by 60%. These two examples show that when the demands of the single market (which requires safe transport and a level playing field for industry) can be brought in line with environmental and health objectives, the EU can have a very positive effect on population health.
some never are. Implementation—making the legislation real—is also hard. It involves changing administrative and clinical procedures to cope with requirements covering everything from medical devices to data reporting and mobile professionals that are disrupted by EU law. Every stage offers opportunities to make health of Europeans worse, or better.

Contributors
SLG and TKH conceived the overall structure of the paper and took primary responsibility for the writing. SLG, TKH, JPM, and MM all contributed text and literature.

Conflicts of interest
TKH is Jean Monnet Professor of European Union Law, conferred by the European Commission. The other authors declare that they have no conflicts of interest.

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