prescribe theophylline and I don't monitor anything.

DMG: I think the message is that it is much more difficult to attain steady state theophylline concentrations than can be predicted from published reports or from hospital monitoring. Perhaps the actual blood concentration is not the relevant parameter; it may be the rate of change of blood concentration that is important. There is evidence that withdrawal of β agonists is followed by rebound airway hyperresponsiveness.¹⁷ If this occurs with theophylline then a fall in serum concentration from 20 mg/l to 10 mg/l could be the most dangerous occurrence in asthma. If we find evidence for this we might have to reopen the whole issue.

In conclusion, we have shown that home monitoring of serum theophylline concentration is possible, that theophylline concentration varies much more at home than in hospital, and that maintenance of theophylline within the therapeutic range failed to prevent life threatening asthma.

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Medicine in Europe

1992 and all that

Tessa Richards

Although 31 December 1992 is, to quote Lord Cockfield, "more of a milestone than a finishing post," the (incorrect) idea persists that something dramatic will happen as the clock strikes midnight.

In the run up to the Maastricht summit polemic about federalism, foreign policy, defence, a single currency, and the recently agreed pact with the European Free Trade Association (EFTA) countries has focused public attention on the future of Europe. The imminence of the summit has also sharpened awareness of the power of the European Community's institutions and how this is set to increase if revised treaties on political and monetary union are signed next month.

General interest apart, should doctors be concerned? How might these changes and the run up to 31 December 1992, with its Orwellian overtones, affect their working practice?

This article is the first of a series on medicine in Europe, in which the *BMJ* will attempt to answer these questions by looking at existing European Community legislation and speculating on the likely effect of what is proposed. The articles emphasise that despite a scant legal basis many decisions which affect health have been made at community level over the past decade or so (box), and if this legal base broadens with the creation of a formal health competence more and more decisions will be made in Brussels. Topics covered will

Overview of some established and draft EC legislation affecting health

Mutual recognition of diplomas—Doctors' directive established in 1975; nurses' 1977; dentists', vets', midwives' 1980; pharmacists' 1980. Directive on vocational training for GPs (1986); minimum two years' training. Future agenda: harmonising specialist training.

Reciprocal arrangements for acute medical care—E111 form. European Council has adopted a recommendation for a European emergency health card.

Pharmaceuticals—Directives on assessing safety and efficacy of drugs (and medical equipment). Recommendations on clinical trial procedures. Draft directives on distribution, advertising, and packet leaflets. Proposed European Medicines Agency (to be set up by 1993). Some moves to iron out drug price differentials.

Food—Directives on additives, food irradiation, radionuclide limits (post-Chernobyl) and growth promoters in meat. Proposed legislation on standards of food hygiene and labelling foodstuff nutrient values.

Environment—Directives on air pollution and water quality. Draft directives on exposure to chemical products, lead, cadmium, pesticides, etc. The framework

of a European Environmental Agency has been agreed. **Health and safety**—Directives on safety in the workplace; personal protective equipment; manual handling of loads; use of display screens (VDUs); exposure to hazardous chemicals, asbestos, and biological agents. Draft directives on protection of pregnant workers and young people.

Consumer protection—Draft directives on the liability of suppliers of services; safety of children's toys and equipment. Rapid alert system for "dangerous" consumer products.

Tobacco—Directives on tar yield and strengthening the warning labels on tobacco products. Draft directive banning tobacco advertising.

Health promotion—Europe against Cancer, Europe against AIDS. Five million ecus allocated (1991) to combat drug misuse. Pending: Europe against Cardiovascular Disease.

Research—Medical and health research programme BIOMED 1 (1990-4), budget >130m ecu, split between research on: disease prevention, care, and health systems; major diseases (AIDS, cancer, cardiovascular disease, etc); human genome analysis; biomedical ethics.

This is the first of a series of articles looking at medical issues in Europe

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include medical manpower and training, the price and control of pharmaceuticals, tobacco, alcohol and drug misuse, nutrition, research, nursing, and ethical and medicolegal issues. Introductory articles will give an overview of the community's institutions, how health matters are currently dealt with, medical representation in Europe, and contrasts between European health systems and patterns of disease.

Setting the scene

The proposal in the draft treaty on political union to give the European Community (EC) a formal mandate for health has been exercising the minds of a growing number of doctors, health policy analysts, and patients' groups throughout Europe. Although the competence is likely to be limited to coordinating the European Commission's existing activities on the health front and implementing more health promotion and disease prevention programmes throughout the community, its adoption will mark an important turning point. For the first time decisions on health can be divorced from the considerations of the single market and a coherent strategy for health developed.

On the negative side, there is concern about the potential such a mandate may provide for future legislation. Can we be sure that legislation on disease prevention, for example, will not spill over into health provision? Few relish the idea of Brussels bureaucrats interfering with the way member states run their health services.

Yet EC "interference" in national affairs is becoming a way of life, as illustrated by the British prime minister's protestations when the EC environment commissioner demanded that work cease on British transport projects.¹ As regularly as the draft directives (box) emerge from Brussels machinery (box), apoplectic responses follow, pointing to the flaws and inconsistencies of what is proposed.² Directives affecting doctors are no exception. For example, the draft directive on the liability of suppliers of services could — unless, as is predicted, the medical sector is excluded — precipitate an avalanche of litigation.³ A second directive, on data protection, threatens the existence of disease registers and could sabotage fund raising by charitable organisations.^{4,5} A third, on the safety precautions needed for work with visual display units (VDUs), has been described as a social albatross around EC member states' necks.⁶

On a more positive note, EC legislation relating to the quality of water has been welcome, as is the proposed ban on all tobacco advertising. Employment draft directives concerning maximum working hours and the rights of pregnant women^{7,8} have been greeted with both enthusiasm and dismay by doctors, for the repercussions on the health service are potentially large. But good or bad the flow of legislation from Brussels, including legislation on health, seems set to increase and it is therefore important to know how it is shaped (figure). The rest of this article focuses on this

European Community laws and other measures

Regulations: laws that are binding, overrides national law, and applies to all member states.

Directives: laws that are binding and lay down compulsory objectives, but member states are left to translate them into national legislation.

Decisions: laws binding only on those member states, companies, or individuals to whom they are addressed.

Opinions and Recommendations: statements, not laws, that are not binding.

The EC legislative process: one illustration

process by outlining the key European institutions and how they were established.

A little history

There is nothing new about the concept of a European identity, nor about a European system of government. Such ideas date back to mediaeval times, but it was only after the second world war that the desire for union and peace overwhelmed centuries of national power struggles. In a move designed to ensure that Germany, with its massive iron and coal industries, would never dominate Europe again the French put forward a plan to unite these industries across national boundaries. This resulted in the Treaty of Paris, signed in 1951 to create the European Coal and Steel Community. Its aim was to place steel and coal production under a common supranational authority embracing the interests of Belgium, France, West Germany, the Netherlands, Italy, and Luxembourg.

Over the next few years moves toward economic unity led, with the signing of the Treaty of Rome in March 1957, to the formation of the European Economic Community. The European Atomic Energy

Community was established concurrently. The three institutions were formally merged in 1967 to become the "European Communities." The dominant institution, the European Economic Community, is now commonly referred to as the European Community or EC. In 1973 Britain, along with Denmark and Ireland, joined the EC. Six years later the European Monetary System, linking member states' currencies to a new currency (the ecu), was founded.

In the 1980s Greece, Portugal, and Spain joined the EC, bringing the number of member states up to 12 and the head count to over 325 million citizens. More controversially, Jacques Delors, president of the European Commission, spelt out his vision of the future: a common defence union, monetary union, reform of the EC's institutional structure, and the removal of all obstacles to trade. To this end a draft Treaty of European Union (to replace the Paris and Rome treaties) was drawn up. Despite legendary opposition from Margaret Thatcher an uneasy compromise was eventually reached and the much diluted Single European Act was signed in December 1985.

The treaty was ratified by every national parliament in 1986; its central commitment was to "the progressive establishment of a free market, in goods, persons, services and capital over a period expiring on December 31 1992." It also gave the EC formal powers to lay down policy to this end and to propose (and enact) legislation relevant to its commitment to improve the environment, encourage technological research and development, and, under social affairs, attempt to smooth out some of the disparities between richer and poorer member states. Specific articles in the treaty have enabled issues of environmental and public health and health and safety at work to be considered.

The institutional maze

The task of achieving the aims of the EC rests with four institutions: the European Parliament, the Council of Ministers, the European Commission, and the

European Court of Justice. The European Parliament holds sessions in Strasbourg, its committees meet in Brussels, and its secretariat is in Luxembourg. The Council of Ministers meets in Brussels and Luxembourg. Although largely based in Brussels, especially in the asbestos ridden Berlaymont, some of the European Commission's administrative staff are in Luxembourg, as is the Court of Justice. This institutional maze, which reflects the EC's history and the reluctance of the governments of certain member states to yield their power-bases, not infrequently leads to administrative chaos. It also throws considerable strain on EC officials; the image of the fraught (predominantly male), leather handbag toting, peripatetic eurocrat is a reality.

THE EUROPEAN PARLIAMENT

Set up in 1979, the European Parliament initially had little more than an advisory role. Its power was strengthened by the Single European Act, and it is now able to amend EC legislation and to approve some of the EC's expenditure, although it has no influence over farm support. Its 518 members, elected every five years, take their seats on the basis of political groups rather than nationalities.

One of the key issues in the revision of the treaty is the proposal to give the European Parliament more power, for it is widely believed that it should share legislative power with the Council of Ministers and the right to set initiatives with the European Commission. This would, it is argued, make decision making in Brussels much more open and democratic. The parliament has its critics, though: "... served by a bureaucracy of 3600 officials which costs more than 500m ecus a year to run. Efficacy is sapped by rivalries of nationality and party politics ... the cost of duplicating or triplicating some jobs and offices ... working in nine languages ... all adds to confusion and expense."

THE COUNCIL OF MINISTERS

The council represents the governments of the 12 member states and its key role is to examine the draft legislation drawn up by the commission and to amend, accept, or reject it. Council meetings take place in Brussels and Luxembourg (behind closed doors), participants changing according to the subject under discussion. Health ministers have been meeting twice a year only since 1986; they have come up against the problem that until recently their dossiers have been dealt with by other ministers. For example, the EC's response to bovine spongiform encephalopathy and its risk to human health was shaped by agricultural ministers—and these ministers, together with those responsible for trade and industry, have dealt with much of the legislation related to pharmaceuticals, tobacco products, and food. With powerful lobbies, the interests of industry have usually prevailed over health interests.

Twice a year the heads of state and government meet at a European summit to take fundamental decisions about the future of the EC. Before the Single European Act a directive could become law only if it had been passed unanimously by council. Since then qualified majority voting (not one member one vote, but a specially weighted formula) has been possible for legislation related to the internal market.

Council is chaired by each member state in turn for periods of six months. Currently the Dutch hold the presidency, which is why the December summit is in Maastricht. The United Kingdom will hold the presidency from July to December 1992 (the last six months before the formal implementation of the single market). The importance of holding the presidency lies in the fact that the country concerned can decide what the agenda will be in response to both the commission's initiatives and its own priorities.

European Parliament poised for more powers

The commission is the most powerful of the EC institutions. It originates draft legislation to put before the council and parliament and implements the resulting directives, and it can issue regulations on its own accord. By close "participation" in the shaping of legislation as it passes through the other EC institutions it has a finger on the legislative pulse at all stages. It manages the funds and common policies that account for most of the EC budget, and through the European Court of Justice the commission can take legal action against member states that fail to implement European law.

Despite its formidable role the commission has fewer than 15 000 staff, and of these a third are translators and interpreters. Furthermore, its key figures, including the 17 commissioners (the "big" countries—France, Germany, Britain, Italy, and Spain—have two each) are appointed, not elected, by member state governments. Each commissioner holds one or more portfolios, which they keep for four years. (The two British commissioners, Leon Brittan and Bruce Millan, are responsible for competition and regional development funds, respectively.) The commissioner who currently holds most responsibility for health matters is Vasso Papandreou, the Greek commissioner: her portfolio consists of employment, industrial relations, and social affairs.

Each commissioner has a small personal staff, or cabinet, which works in (often uneasy) parallel with the commission's permanent civil servants. They work in 23 different departments, known as Directorates General or DGs, under director generals who head their own hierarchy of staff. Although a few of these directorates are overstaffed, most—including some of those concerned with health—are run on a shoestring with insufficient staff to deal with burgeoning workloads. Whether the *Economist's* view that the Berlaymont is badly run and its staff deeply unsettled is justified is a moot point,¹⁰ but when I visited Brussels in June the corridor talk was dominated by how the staff were going to organise, and deal with the repercussions of, a strike.

THE COURT OF JUSTICE

The European Court of Justice is in Luxemburg and its judiciary is drawn from all member states. European law takes precedence over national law, as the controversy over British fishing rights illustrated.¹¹ Cases can be brought by individuals, companies, governments, and the commission. The court's workload is immense, and the time taken to produce a judgment is often long. Many countries including Britain are failing to implement an appreciable proportion of established European law; only 37 of the 126 single market laws have been passed by all member states.¹²

ECONOMIC AND SOCIAL COMMITTEE

Another institution with input in the legislative process is the Economic and Social Committee. This consultative body represents employers, trade unions, and other interested groups; it has comparatively little power.

Fragmentation of the health bureaucracy

Anyone attempting to understand how health issues are dealt with in Brussels, to get their views across to the commission staff who are shaping draft legislation, and follow the passage of the legislation through the EC institutions must be prepared for frustration. There is no commissioner for health and no one department deals with health issues, so they may have to run the gauntlet of officials in directorates dotted all over Brussels and Luxemburg (box). This is difficult enough

Departments in the European Commission concerned with health

DG I:	External relations (Latin America, cocaine, etc)
DG III:	Mutual recognition of diplomas, including doctors, nurses, etc Pharmaceuticals Food Medical equipment Standardisation
DG V:	Health and safety Public health Europe against Cancer Europe against AIDS Nutrition
DG VI:	Nutrition Pesticides Veterinary medicine
DG VIII:	Health in developing countries
DG XI:	Environment Consumer protection
DG XII:	Medical health research Biotechnology
DG XIII:	Advanced informatics in medicine
CPC:	Consumer affairs

from a base in Brussels, but immeasurably more so from a distance. Furthermore, as national medical associations, departments of health, and others have learnt to their cost, protestations from single member states carry little weight with the commission.¹³ The combination of administrative fragmentation, inadequate communication between directorates, and understaffing—coupled with a noticeable shortage of high calibre, suitably trained and experienced staff—has not been a good recipe for legislative vision. And with no set brief, small wonder that the EC's approach to shaping health policy has been criticised as uncoordinated and ineffectual.

Conclusion

If, as expected, the EC acquires a formal competence for health and a commissioner for health is appointed it should become easier to access and influence the commission on health matters. Some internal restructuring and recruitment within the commission would also help. In recognition of pending change everyone concerned with health seems to have "woken up to Europe" and the need to get their voices heard in Brussels. There is much talk of the need to fill the health policy vacuum and define which health matters are best tackled at community level and which should remain a matter of national concern. Non-professional and non-governmental organisations have been as active on this front as ministers of health and organisations and associations representing doctors.¹⁴ What has been achieved beyond the rhetoric is hard to gauge, but at least the ball is rolling.

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