by which we administer care, offers a plausible mechanism. Indeed, we have already taken the first step in our attempts to set standards or guidelines for the process of medical care. It has even been recognised that standards will have to be regularly reviewed and updated on the basis of new knowledge. When this process of review has been accepted and incorporated into practice, and when we have expanded the review of process to include processes of the organisation and delivery of care (as we discuss in next week's issue) we will have achieved TQM.

Modern medical care is a complex enterprise entailing interactions among doctors, nurses, and other health professionals; complex information systems; an immense array of pharmaceutical products; and complex devices, equipment, and rules of procedure. For good results these complex elements must be assembled effectively, and improvement depends on the processes of care and management that orchestrate these many elements. Such orchestration is not easy. The NHS reforms are designed to increase the freedom and willingness of hospitals to identify and seize opportunities for better coordinating of the elements of care. TQM is a method for achieving just that.

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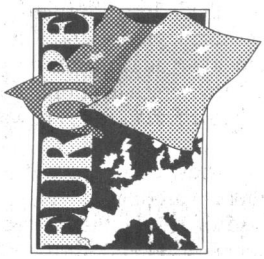
Medicine in Europe



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

Prescribing in Europe—forces for change

David Taylor

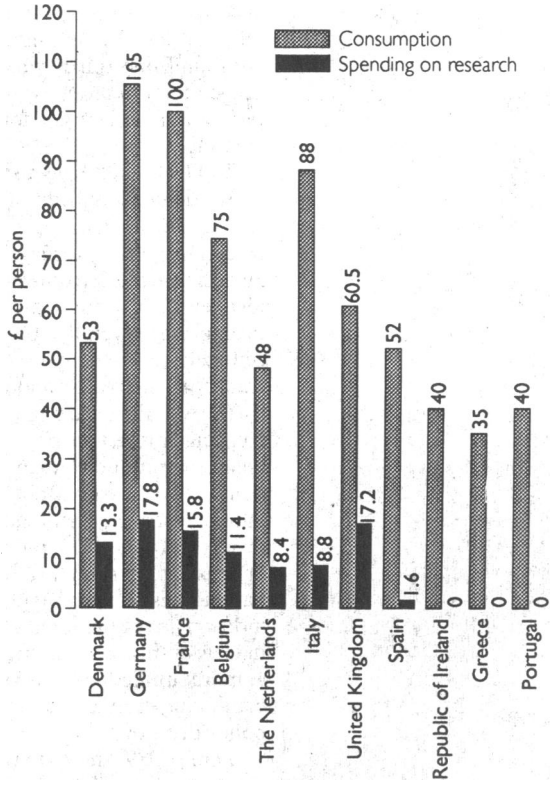
Legislation existing in or planned by the European Community (EC) already affects the pharmaceutical sector in a wide variety of ways (box, p 241). It relates not only to how medicines are licensed, priced, labelled, and distributed but also to how they are manufactured and how clinical trials may properly be conducted.[1,2] Ultimately, every aspect of supply, from the post marketing monitoring of drug safety to the funding of research, may be influenced more by decisions made in Brussels than those agreed in individual member states.

The development of the EC single market is primarily intended as an economic measure. In the context of pharmaceutical trading it also has the potential to bring about considerable changes in the differing medical cultures of the EC's member states, influencing both the prescribing rights of the community's 600 000 practising doctors and the access to treatment of many of its 350 million citizens.

This article examines the extent of and reasons for the existing variations in consumption of medicines in Europe and the nature of the challenge facing those wishing to build a more unified EC medicines market. It then assesses the importance of current political debate about issues such as the costs of and access to medicines, safety of medicines, and the promotional standards of drug companies.

Differences in use of medicines among EC states

All international comparisons may be subject to distorting factors. Nevertheless, the data presented in the figure and the table are broadly consistent with a range of sources.[3-5] They give an overview of differences in spending on medicines and dispensing volume in the EC. Key points about the European pharmaceutical market include:



Consumption of pharmaceutical products at manufacturers' prices and spending on research, per head of population, 1989

(1) Overall, richer countries spend more of their gross national product on health than do poorer ones, and in cash terms will usually spend more on medicines. Yet less affluent countries like Greece and Portugal spend much more on pharmaceuticals relative to their

King's Fund Institute, London NW1 7NF
David Taylor, BSC, *fellow in health policy analysis*

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Costs and consumption of pharmaceuticals in EC countries, 1989

Country	% Of gross domestic product spent on health services[a]	% Of health resources spent on pharmaceuticals	% Of gross domestic product spent on pharmaceuticals	Relative price of medicines, 1990 (EC=100)[b]	Implied volume of pharmaceutical consumption (UK=1)
Denmark	6·3	6·8	0·47	129	0·8
Germany	8·2	10·6	0·87	128	1·6
France	8·7	10·8	0·94	72	2·7
Belgium	7·2	9·9	0·71	89	1·6
Netherlands	8·3	5·5	0·46	133	0·7
Italy	7·6	12·5	0·95	80	2·1
United Kingdom	5·8	11·5	0·67	117	1
Spain	6·3	13·8	0·87	73	1·4
Republic of Ireland	7·3	10·8	0·79	132	0·6
Greece	5·1	20·9	1·06	74	0·9
Portugal	6·3	23·6	1·48	68	1·1

Column 2 relates all pharmaceutical consumption (including over the counter drugs) valued at manufacturers' prices to all health care spending, public and private. In columns 1 and 3 gross domestic product is measured at market prices. The index of prices used is based on retail costings. Countries are ranked in order of gross domestic product per head, compared at 1989 exchange rates unadjusted for internal purchasing power variations. Population aged ≥65 (high drug users) ranges from 11% in the Republic of Ireland to nearly 16% in Germany, United Kingdom, and Denmark.

total health budgets than do better off states of the community.

(2) On a country by country basis Denmark is an illustration of a nation that combines lower than average domestic pharmaceutical consumption and spending with high medicine prices. France, by contrast, has low prices but high domestic usage and high medicine costs per head. The proportion of Danish gross national product spent on medicines is half that in France.

(3) In general, the EC nations with the highest medicine prices at home also have the most successful foreign trade records (the Netherlands is an exception) and the lowest volumes of domestic prescribing (Germany is an exception).

(4) In northern EC states, such as the United Kingdom, Denmark, and Germany, over the counter medicine sales account for nearly a fifth of the total value of the medicines market. In Portugal, France, and Italy over the counter medicines represent only 5-10% of sales. (In the United States the equivalent figure is around one third, which implies that the EC over the counter market will expand during the 1990's, particularly if charges for prescription medicines are extended.)

(5) The United Kingdom combines relatively modest domestic consumption of and spending on medicines with a strong balance of trade and unusually high research spending. Largely because of Department of Health controls introduced in the 1970s it has unusually low levels of domestic spending on pharmaceutical promotion. Overall, about 10% of all NHS pharmaceutical revenue goes on promotion; equivalent European figures are about 15-20%.

(6) All European governments are showing increasing interest in promoting value for money with regard to publicly financed use of pharmaceuticals. Some new measures may limit doctors' prescribing; others restrict patient access to publicly purchased drugs; and yet others inhibit companies' abilities to sell or promote certain products. But at the same time nations wish to maintain or increase pharmaceutical industry investment within their borders, particularly in view of the manufacturing plant rationalisations that a more unified EC market may encourage. These conflicting motives may lead to apparently paradoxical policy decisions.[6]

Since 1989 there may have been some limited changes in the balance indicated in the table. For instance, government interventions in Germany have reduced some medicine prices there, while prices permitted in Italy for new products have been increased.[7] But the general position has remained surprisingly stable during the past three decades.

One important reason why this has been so is that the differences between European countries' prescribing patterns are based on deep rooted variations in medical culture and training rather than just the effects of contrasting price and profit controls for medicines.[8,9] Even so, such controls contribute to dramatic cost variations. In 1989 the Brussels based Bureau Européen des Unions de Consommateurs reported extreme illustrations of price distortion: Zyloric was 10 times more expensive in the United Kingdom than in Spain; Indocid 10 times more expensive in the Netherlands than in Greece; and Microgynon eight times more expensive in Germany than in France.

The influence of professional traditions is reflected in the German acceptance of combination medicines, which British doctors would normally regard as unscientific and in some cases even unsafe. This partly accounts for the large number of branded medicines available in Germany.[7] The special cultural importance of issues relating to the heart is a possible reason why mild cardiac insufficiency and hypotension are regarded as diagnoses requiring treatment in Germany more frequently than in the United Kingdom.[9] Differing levels of promotional effort may also help to explain why, in the case of hypertension treatment, German doctors use diuretics more than their colleagues elsewhere in Europe. Similarly, British and German doctors often prescribe β blockers, whereas angiotensin converting enzyme inhibitors have gained a more dominant market position in Italy and France.[10]

In France patients apparently question their medical treatment less frequently than do patients in the United Kingdom. This may be one of the reasons why France now has the world's highest consumption of benzodiazepine sedatives and allied drugs.[11] In the United Kingdom this class of medicines is dispensed at nearly half the level recorded a decade or so ago. Whereas one French person in three took a hypnotic or tranquillising drug last year, the British figure is now probably less than one in ten.

For many years French doctors have also displayed a tendency to prescribe peripheral vasodilators. Next door in Italy, by contrast, use of tranquillisers has always been limited and peripheral vasodilators are less popular. Nevertheless, somatically expressed anxieties (and concerns about liver functioning in particular) have led to high sales of prescribed tonics and hepatic protectors.[8]

The challenge facing Europe

The task facing agencies such as the European Commission in establishing a single European pharmaceutical market during the 1990s is daunting. It involves overcoming protectionist national structures which create waste and impair competition without—through pressing too hard for free trade and pharmaceutical cost savings—undermining companies' abilities to support research on medicines. European policy makers also need to try to ensure that over-enthusiastic moves to greater market unity do not cause the local values and preferences of patients and their physicians to be ignored.

For example, the perpetuation of wide price variations in medicine across Europe has obvious disadvantages, not the least being that it creates a sense of unfairness. The resultant practice of parallel importing* should help to level prices in time, to the extent that firms are free to adjust them. But it may promote lower than expected savings for health care systems or patients because of profit retention by middle men. And parallel importing does cut research based pharmaceutical companies' earnings.

*Buying cheaply a given product in one country and selling it at the higher price in another. This affects little more than 1% of the value of trade in medicines in the EC overall but accounts for around 7% in the United Kingdom.

Furthermore, too rapid transition to even pricing across Europe might have unfortunate effects on countries with low incomes or a high use of medicines, or both. Dismantling local price control schemes could encourage governments to use other methods of making savings in their pharmaceutical budgets—for instance, by raising charges to patients for medicines, which could cause real problems for poor communities.

Existing or proposed approaches to prescribing cost limitation in the EC include the following examples.

Major EC pharmaceutical initiatives

1965	First directive on human medicinal products established a general framework for subsequent national and EC legislation
1975	Second directive led to the establishment of the EC's Committee for Proprietary Medicinal Products in 1976. First EC licensing procedures thus established
1975-85	Limited developments—for example, in 1983 a council recommendation introduced preclinical and clinical guidelines, and medicine information and data requirements were amended
1985	The Delors white paper put forward 13 proposals relating to pharmaceuticals
1987	The biotech and high tech directive established new means of authorising and protecting products that might not have patents. It established the first pan-EC arrangements for licensing certain types of medicine
1989	The "transparency" directive, which came into force in January 1990, sought to ensure that national decisions on medicine pricing and reimbursement are fair and made on a visible basis. It laid down a framework for cooperation and information exchange and required the commission to present before January 1992 further proposals to eliminate distortions in the EC market
1991	Directives on the rational use of drugs, affecting wholesaling, harmonisation of legal status, and labelling and package information are nearing adoption. Also, a directive on pharmaceutical advertising has been prepared: it affects matters such as financial inducements and the distribution of free samples to professionals as well as advertising to the public, but will not now prevent companies from sponsoring medical meetings
Under consideration	Future systems for drug authorisation, which at first will probably involve three approaches: a European Medicines Agency will be established in an as yet undecided location to handle centralised applications; the commission's proposals on supplementary protection certificates for medicines patents are under consideration, along with suggested controls on homoeopathic medicines and international drug testing harmonisation; a consultation document on clinical trials, aimed at controlling fraudulent practices and raising ethical standards, is in circulation. There are no proposals yet on the control of postmarketing surveillance initiatives and allied marketing interventions other than those in the "future systems" package

Product by product price control: This is the most common EC model, used in France, Belgium, Italy, Spain, Greece, and Portugal. In many cases it has been used to support local industry.[12] (Reference pricing, now being introduced in Germany and the Netherlands, sets a basic price for entire drug classes. More expensive products in a given group have to be paid for directly by patients.)

Company by company profit and cost control—This is unique to the United Kingdom, where the Department of Health's pharmaceutical price regulation scheme has helped to achieve low promotion spending coupled with high research outlays. Details of the current scheme may, however, need to be modified in the face of the increasing Europeanisation of medicines trading in the United Kingdom.

Positive and negative lists—Examples of one or the other now exist in all EC nations. Their effect is either to restrict prescribing for patients of the public health care system to products approved on positive lists, or to block their access to medicines on negative ones. Controls over entry of products to such national lists—or local formularies—may limit the influence of the medical profession. (The introduction of needs clauses in medicine licensing procedures, as in Norway, can be seen as a form of strict negative listing.)

Patient copayment systems—Charges may help restrict patient demand. Countries such as Belgium, Denmark, Greece, Italy, and Portugal vary the amount of prescription payment due inversely with the perceived value of the medicine. But high levels of exemptions to charges, as in the United Kingdom, decrease the impact of such systems. So too do back up private insurance systems to cover public service costs, as is most obvious in France.

Generic or therapeutic substitution, or both—Generic prescribing has been strongly encouraged in Denmark, the Netherlands, the United Kingdom, and to a lesser extent Germany. Mandatory generic or therapeutic substitution (in which doctors' prescriptions are filled with products other than those actually specified) does not yet exist in the EC.

Prescriber budgets—Pioneered in the United Kingdom's fundholding and indicative prescribing schemes, prescriber budgets are designed to increase prescribers' awareness of medicine prices without imposing rigid limitations on their judgment. Provided that the sums allocated are adequate and provision is made for unpredictable cost increases, this approach should combine the pursuit of cost restraint with respect for professional and consumer therapeutic choice.[6]

Privatisation—Encouraging the use of over the counter medicines and the private purchase of prescription drugs obviously shifts costs away from the public purse. The United Kingdom already has a sizable over the counter market, although no European country has—in relative terms—as great a volume of non-prescription sales as the United States. Denmark has a large over the counter market, coupled with private purchase of about a quarter of all prescribed medicines.

Future threats and opportunities

Some commentators fear that attempts to create a single European market will break down medicine safety controls at a national level in a way that might benefit trade at the expense of consumer wellbeing.[13] The creation of the proposed new European Medicines Agency and allied bodies could reduce the importance of local institutions like the United Kingdom's Committee on the Safety of Medicines[14] and with it the influence of national medical establishments. This might make it easier for powerful industrial and

allied interests to dominate regulatory activities in the EC. As and when the agency comes into being in or around 1993 (the site is not yet decided, but it could be in the Netherlands) care will have to be taken that its membership and working practices are as open and representative of informed public interests as possible.

It would be wrong to overstate, however, the risk of medicine safety standards being undermined by future EC arrangements for licensing. As suggested above a more potent threat to community wellbeing might stem from a weakening of medical control of public health care prescribing coupled with increasing pressures on consumers to pay directly for their medicines. Should this take place there will be a risk of depriving poorer people in Europe of access to effective care. This would be counterproductive in both social and financial terms, in that it could cause otherwise preventable ill health while undermining consumer confidence in existing provisions.

Those in government, the professions, and the pharmaceutical industry who are at present involved in lobbying to determine the structure of the future unified EC market should be aware of such dangers.[15] As is shown by the United Kingdom's record of keeping drug industry promotion spending down to about half the percentage of domestic turnover in countries such as France and Germany, there may be opportunities for reforms across the EC. But it would be foolhardy to interfere too quickly or too radically in structures that over the past 40 to 50 years have served public interests well. Compared, say, with eastern Europe's past record of low innovation and inadequate prescriber and patient access to drugs, that of the West is one thankfully to be preserved.

It is important to maintain the optimal amount of prescriber freedom and affordable access to medicines for all patients. Greater sensitivity to the price of medicines throughout the EC should not be gained at the expense of impairing society's ability to value effective treatment for everyone.

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Health and the Environment

Swimming—the hazards of taking a dip

Alison Walker

British Medical Journal, London WC1H 9JR
Alison Walker, MRCP, *former editorial registrar*

Correspondence to:
Department of Paediatrics, St Mary's Hospital, London W2 1NY.

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> In summer it [the sewage] causes a visible brown buoyant stain extending from the outfall pipe and spreading its way along the bays as it is brought in by the incoming tide.
>
> Sons of Neptune bathing club, Scarborough[1]

Scarborough is not the only resort where holidaymakers have to contend with sewage in the sea. Short Victorian outfall pipes still discharge sewage from coastal towns all round Britain. Leaving Britain's shores and holidaying in the Mediterranean provides no escape as the beaches there are no better. The picture, however, is changing. The longheld belief that the sea can absorb, dilute, and disperse everything discharged into it is now seen as wishful thinking and is no longer accepted. Throughout Europe resorts are starting to be cleaned up as European politicians begin to take notice of public opinion and growing scientific evidence incriminating contaminated sea water as the cause of symptoms in holidaymakers.

Health risks from swimming in seawater

Until a few years ago the British government relied on research from the 1950s to form the cornerstone of its policy on bathing water. The research was performed by the Public Health Laboratory Service and looked retrospectively at poliomyelitis (a serious problem at that time) and enteric fever in sea bathers. The conclusions were reported jointly by the laboratory service and the Medical Research Council and showed that, with the exception of a few heavily polluted waters, the risk to public health from swimming in sea water contaminated by sewage could, for all practical purposes, be ignored.[2]

Things have moved on since the 1950s, and although the laboratory service's studies were carefully conducted, they are now seen to be limited by the techniques of the time. The risk of swimming in heavily polluted water remains undisputed and carries with it the risk of contracting infections such as typhoid, shigellosis, leptospirosis, and hepatitis A. More contentious, however, is the possible link between minor infections and swimming in sea water that is only moderately contaminated.

Establishing a link between minor illnesses such as gastroenteritis and ear, nose, and throat infections and swimming in polluted sea water is extremely difficult because these conditions are so common and may have various causes. Some headway has been made from large epidemiological studies which have compared the symptoms of swimmers with those of people who stayed out of the water.

One of the first studies to show a relation between sea bathing and minor symptoms was a prospective cohort study carried out in the 1970s by the United States Environmental Protection Agency.[3] The work was performed by Victor Cabelli in three different resorts—New York City, Lake Pontchartrain, Louisiana, and Boston—over five years. Altogether more than 25 000 people took part. Those bathing were