Impact of the European Community on medicine

Report of a conference

MAURICE H. LESSOF, MD, FRCP
Emeritus Professor of Medicine, University of London

Conferences are meant to focus the mind — and this one did. The year 1992 will be upon us faster than we think, and the ‘harmonisation of goods and services’ will in due course have an important impact on health care practices. While nobody believes that the Brave New World will be ushered in overnight, a number of changes will inevitably make an impact on the future of medicine.

How the system will work

Dr Jeremy Metters, a Deputy Chief Medical Officer, pointed out that throughout Europe, as of January 1991, there will be mutual recognition of professional qualifications obtained after at least 3 years of training. Health issues do not fall strictly within the terms of the Treaty of Rome but the European Parliament and Commission have been increasingly willing to discuss them, and Health Ministers now meet regularly. The Council of Health has become increasingly active since 1985 and has made proposals on a number of health issues, including the prevention of cancer, AIDS, alcohol abuse and the management of disabilities. However, economic considerations rather than health issues will decide topics such as the harmonisation of tobacco and alcohol taxation. If physicians wish to see a stronger medical input into the convoluted workings of the Brussels machine, they may have to start by learning how the system works.

Medical manpower

Sir Robert Kilpatrick, President of the General Medical Council, noted the almost unique position of the United Kingdom in having its own self-regulating body. As chairman of the GMC Education Committee, Dr D. Shaw described in detail some of the problems which can arise from organisational differences. The number of qualified doctors has increased fourfold in Europe in the past four decades, while population growth has been relatively small. The legal recognition of another country’s certificates of qualification will not present an immediate problem, since appointment committees will examine both the experience and the qualifications of a candidate. With a 16% unemployment rate for European doctors, however, the pressures towards a greater migration of doctors can only increase. The European junior doctors’ committee has already drawn attention to the problems of manpower and has vigorously emphasised the need for more trainers. It is apparent that there are contradictory manpower policies in different EC countries, ranging from tight control in the United Kingdom to what appears to be an almost unlimited production of medical graduates in at least one EC country. Although the number of doctors who qualify in Europe has halved, it is still substantially in excess of Europe’s needs. Manpower controls which lead to deficits in Britain could therefore encourage migration from other parts of the European Community.

Specialist accreditation

There are other discrepancies between Britain and the majority of European countries which categorise medical posts in a different way. Instead of Royal Colleges, other European countries have mono-specialist committees which deal with accreditation. They have fewer specialist diplomas but their general requirements tend to be rigorous. If harmonisation is to be attempted, the Union of European Medical Specialists, the European Group of Junior Hospital Doctors and the practitioners of public health medicine will have an increasingly prominent role, not only in dealing with specialisation but also in medical ethics, advertising and informed consent.

The Commission’s view

Two speakers represented the Commission of the European Communities. Mr S. Allman, Secretary of the Advisory Committee on Medical Training and a member of the Commission of the European Communities, pointed out that the Community has economic matters as its chief remit. Since there is no EC ‘officer for health’ and therefore no organisational structure, a number of the 25 Directorates General have to deal with medical matters. A watchful eye is nevertheless
kept on the training requirements for a doctor’s basic qualifications and some 50 specialties. Countries such as France which require a long postgraduate training will have to accept the specialist training obtained in less rigorous countries. The training requirements for specialties such as occupational medicine have now been recognised, and consideration is being given to the training needs of oncologists. However, specialist groups concerned with surgery of the hand and forensic medicine consider that the legal training requirements are too lenient and are seeking additional voluntary agreements. This trend is likely to continue.

Research

Research has become the third highest spending area in the EC. Dr A. J. G. Dickens, head of the Medical Research Division of the EC, commented that its importance seems to be rising as the agricultural budget falls. Medical and health research has a budget of 64 million ECU (£48 million sterling) and is expanding rapidly. Its first priority is the coordination of research projects that cross national boundaries, but some direct funding may now be added. The topics covered include cancer (for which some fellowships are available), AIDS (including drug research), age-related problems, disabilities, the effects of environment on health, health services research, tropical medicine and medical technology. Mrs Wendy Light, European Liaison Officer, is available to answer queries, at the UK Research Council’s European office (Rue de Loi, 83 Box 10, 1040 Brussels, Belgium. Telephone 230 5275, Fax 230 4803).

The Assistant Director of the CIBA Foundation, Dr G. R. Bock, gave some insight into the system for awarding ‘concerted action’ research grants for collaborative projects. It is necessary to assemble a project management group, formulate and submit proposals to Brussels, and be prepared to hold an exploratory workshop. The relevant committee — including a British representative — might then consider awarding a reasonably generous grant to cover meetings for the project management group and for the coordination of research. Until now, research personnel have not been funded.

Medical ethics

The afternoon session was concerned with ethical and legal aspects and with the complex changes taking place in the drug regulatory systems. Professor G. Dunstan, Emeritus Professor of Moral and Social Theology, noted that ethical problems have become even more complex in a European setting than in a national forum, but past assumptions have been changing rapidly and there are new opportunities which need consideration, eg the opportunity to study the human genome. The German nation has reason to fear Nazi attitudes to eugenics, and the Vatican has strong views on genetic studies, embryo research and artificial insemination. Those who share these views favour restrictive legislation, but others point out that attempts to ban research on ethical grounds would have prevented a number of medical advances which have helped sterile women to conceive and have helped carriers of a genetic defect to have a normal child. There cannot be a rapid resolution of these differences, and proposals continue to be put to the European Community for restrictions to be placed on research topics which the Commission has, in the past, approved.

The law

The priorities of the law are somewhat different from those of the ethicist, since the lawyer is most concerned with the general aim of protecting the free movement of goods and people. This is not always to the liking either of the industrialist or of the medical profession. Professor G. Dworkin, of Queen Mary College, London, noted that, as with other goods, drugs could not legally be stopped at national borders within the EC unless public security or health is affected. The Court has ruled against a pharmaceutical company which objected to the prescription of cheap generic drugs imported from another EC country.

The free movement of doctors poses additional problems. Doctors from outside the EC might have the right to practise in a particular country, like the doctor who qualifies in Macao and has the right to practise in Portugal. Such doctors will, however, have no right to practise in any other European country. Nevertheless, in 1989 more than 1,000 newly registered doctors in the UK who had qualified in another country. This was more than 1 in 6 of the new registration, as against 1 in 100 in 1977 when the regulation governing freedom of movement was first introduced. It remains to be seen whether legal problems will now arise over questions of professional competence, litigation for negligence, language problems or breach of confidence. However, since competition must be allowed, there is a prima facie case for believing that private insurers and others will have to recognise the qualifications obtained in another country.

Drug regulatory systems

Dr Keith Jones, Director of the Medicines Control Agency, commented on the substantial differences in drug usage in different parts of the EC. There are differences in the strength of insulin, the use of bronchodilators, and the customary length of drug treatment given for depression. The United Kingdom is also unusual in providing data sheets and in its extensive provision of drugs at hospitals rather than through outside pharmacists. Harmonisation through the creation of a European Medicines Agency will be slow in coming, but existing control groups are constantly being strengthened and there is an increasing tendency to refer problems to experts. The regulatory agencies employ substantial numbers of staff. While the 500+ in West Germany and the 300+ in the UK are
Attempts to harmonise throughout Europe have, however, been a source of endless frustration. Since 1976, multi-state application procedures have been available which, in the absence of local objections, should lead to the almost automatic approval of a drug in several states within 60 days of its first licensing. In every case objections have been raised, so approval never takes less than 6 months; in Italy it takes 26 months. The monitoring of side effects also has its problems. It might be thought that hepatic toxicity does not exist in France, while cardiovascular side effects, which are fashionable in Sweden and the United States, are equally unfashionable in the UK and Holland.

Professor Michael Rawlins, Professor of Clinical Pharmacology at Newcastle, felt that British participation in EC drug regulation has produced both gains and losses. The 'yellow card' reporting system has undoubtedly provided early warning of drug hazards; use of the cards has almost trebled in 25 years and more than 40 are now submitted for every million prescriptions. The proposals now drafted for the European Community may help by introducing, into the UK, the conditional licensing arrangement which is available elsewhere and obliges the manufacturer to carry out post-marketing surveillance. The draft regulations will also improve the package inserts which accompany drugs, and will provide exclusive marketing rights for 10 years. There will be some loss of sovereignty. National Ministers of Health will be legally responsible for decisions of the Commission, albeit with a right to suspend a licence on grounds of public health. It remains to be seen whether legal clarity and accountability, scientific objectivity and pharmacovigilance can be maintained under the new system.

Those who attended this conference proved to be a lively audience and asked many questions to which there were no easy answers. In accepting this, those who represented the Commission were always helpful, informative and frank. They made it clear that there is still a need to challenge false assumptions and to look for improvements but suggested that those who wish to influence events will only succeed if they work as Europeans within an EC framework. In medicine, as in other walks of life, there may be a lesson to be learned.

This conference was held at the Royal College of Physicians of London on 10th May 1990.

Discs

The Journal will now accept discs to the following specifications:

Macintosh 3½ inch, using Microsoft Word

OR

5½ inch, 360K byte floppy disc with MS-DOS

Your discs should always be presented with two copies of the manuscript. Please ensure that your references accord exactly with Journal style. Please see Notes to contributors printed elsewhere in the Journal.