London—the European centre of excellence

At the Brussels Summit at the end of October 1993, the leaders of the European states agreed that the European Medicines Control Agency should be located in London. The agency will be a prestigious European body with overall responsibility for ensuring the safety of medicines. It will evaluate the quality, safety and efficacy of medicines throughout Europe under a dual registration system:

- A centralised procedure which will be mandatory for products derived from biotechnology and optional for other ‘high-tech’ medicines. Applications from manufacturers will be made directly to the agency. If marketing approval is granted, a single authorisation will be automatically valid in all member states—that is, there will be a single European Union-wide licence.

- A decentralised procedure for all other medicines, under which approval in one member state will be automatically recognised by other member states within the European Union. In the event of disagreement between the member state initially granting approval and other states in which approval is requested, the agency will make a final and binding decision.

The examination of registration applications will be made by the existing Committee on Proprietary Medicinal Products (CPMP) and its veterinary equivalent, the Committee on Proprietary Veterinary Products (CVMP). These two committees will be reinforced, and will carry out their assessments through selected experts drawn from across Europe.

The whole system will operate as shown in Fig 1.

In addition to its primary role of assessing medicinal products, the agency will also have the responsibility for:

- monitoring adverse drug reactions;
- establishing the credibility of agency standards throughout the world;
- promoting technical cooperation between member states;
- encouraging research and innovation;
- facilitating the establishment of a European database for medicines.

The agency is due to open for business on 1 January 1995, although the exact location in or around London has yet to be decided and the board of management is still to be appointed. The board will comprise two representatives from each of the 12 member states, two from the European Commission and two appointed by the European Parliament. Half the 28 members will be primarily concerned with the control of human medicines and half with veterinary products. One of the first tasks of the board will be to appoint the agency’s director who will be responsible for its day-to-day operations.

In preparation for the eventual establishment of the agency, the management consultants Touche Ross were commissioned to study its structure, operations and costs. They estimate that 50 applications for new medicines will be handled through the centralised procedure in 1995, increasing to around 80 in 1997 and falling back to 60 in 1999. At the same time there will be submissions of 100 variations (i.e., new dosage forms, changes to dosages and indications, etc.) in 1995. This figure is expected to increase to over 1,000 by 1999. Applications under the decentralised procedure are predicted to be 200 in 1995, rising to 600 by 1999.

To handle this workload, an eventual agency staff of about 300 is foreseen. As with all European Union bodies, the senior staff will be appointed on a quota basis from all 12 member states. Since the agency will be a pan-European body, a significant number of employees will be interpreters and translators to ensure that discussions and documents are available in all nine existing European Union languages.

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The agency's setting up costs are estimated at £3.4 million, and the running costs are forecast to rise to some £42 million by 1999. These costs will be met mainly by registration fees paid by pharmaceutical companies and partly by funding from the European Commission. The level of fees and the balance between industry and Commission are still under discussion.

The decision to locate the European Medicines Control Agency in London has been supported by the pharmaceutical industry worldwide. A survey of top UK, continental and US pharmaceutical companies showed an overwhelming preference for London—four times as many senior executives supported London than any of the other six countries hoping to house the agency. The London location will attract many overseas companies which are expected to set up registration offices in or around London to be near the new agency. Several thousand new jobs could be created in the London area as a result.

During the lobbying campaign for the agency, the Secretary of State for Health, Mrs Virginia Bottomley, stated:

'A successful European medicines evaluation agency will benefit all the people of Europe. It will help to make medicines safe and it will help to strengthen the important European pharmaceutical industry.'

We are confident that this will happen.

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**Professional and managerial aspects of clinical audit**

*Edited by Anthony Hopkins*

When medical audit was introduced in 1989, it was primarily as a means whereby a medical team could regularly evaluate the quality of its service to patients. More recently, however, audit has taken on a wider, clinical remit to reflect the involvement of other health professionals in the overall care of patients.

This book, based upon a conference organised jointly by the Conference of Medical Royal Colleges and their Faculties in the UK and the Institute of Health Services Management, explores how best to involve health professionals and management jointly in clinical audit, whilst addressing some of the tensions raised in relation to clinical confidentiality and professional performance. The book is introduced by the Government's Chief Medical Officer, and contains chapters by the President of the General Medical Council, senior clinicians, hospital managers, information specialists and others.

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**ROYAL COLLEGE OF PHYSICIANS**

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