*Br. J. clin. Pharmac.* (1992), **33**, 365–367

# Roles and responsibilities of clinical pharmacology: government and governmental bodies

MICHAEL D. RAWLINS
Wolfson Unit of Clinical Pharmacology, The University, Newcastle upon Tyne, NE1 7RU

## Introduction

Drug treatment is the primary therapeutic approach to the management of most patients who use the national health service (NHS). It is hardly surprising, therefore, that expenditure on drugs, currently in excess of £2bn per annum in the UK, is a significant (around 10%) proportion of total NHS costs. Safe, effective and economical use of drugs—the basis of rational prescribing—is thus central to the efficiency of the NHS, and clinical pharmacologists should play a critical role in both the central and the local provision of health care.

## Central government

The UK government has three interrelated concerns with drugs and prescribing. First, it has a responsibility to control the NHS drug bill. It attempts to achieve this, in part, through the Pharmaceutical Price Regulation Scheme which involves balancing the financial interests of the NHS against those of the general UK economy particularly as it is represented by the pharmaceutical sector. This is not an area in which clinical pharmacologists play any role and I will not discuss it further. Second, central government has a responsibility to encourage rational prescribing and so ensure that drug use, within the NHS, gives value for money. This responsibility stems from the obvious need to show parliament, and the public, that prescribing is both economic and effective. It is clear, however, that central government (irrespective of its political complexion) has not found this easy and, to a considerable extent, has now shifted this responsibility to Regional, District and Family Health Service Authorities. This change, presaged in the White Paper 'Working for Patients', and given a statutory basis in the NHS and Community Care Act (1990), offers a real challenge to clinical pharmacologists and will be discussed later. Third, central government has the responsibility to regulate the pharmaceutical industry through both domestic (Medicines Act) and European (EC Directives) legislation.

The Medicines Control Agency, the executive arm of UK drug regulation, is part of the Department of Health and answerable to the UK Health Ministers. It is responsible for ensuring that marketed drugs are of good quality, are effective in the conditions for which they are promoted, and (relatively speaking) are safe. The techniques and scientific approaches of clinical pharmacology thus play a central role. The Director of the Medicines Control Agency is himself a clinical pharmacologist and the Agency's staff include a substantial number of individuals trained in the discipline. Moreover, although other members of the Medicines Control Agency's professional medical staff have specialist expertise in areas such as microbiology, endocrinology, gastroenterology, gynaecology and haematology they all need a broad knowledge and understanding of clinical pharmacological principles to function effectively.

The Medicines Control Agency and the Licensing Authority (the group of ministers vested with statutory powers under the Medicines Act), are advised by what are refered to as 'Section 4 Committees' (Committees set up under Section 4 of the Medicines Act) of which the Committee on the Safety of Medicines is the most widely known. Clinical pharmacologists play a major role in the deliberations of the Committee on the Safety of Medicines and its Subcommittees. They give an important perspective on the significance of preclinical pharmacological and toxicological studies; they have particular skills in assessing the results of phase 1 and dose-titration studies; they can critically evaluate the design and interpretation of clinical trials; and they have long experience in trading risk for benefit. Specialists in parallel disciplines such as toxicology, epidemiology and biostatistics are also necessary to provide balanced advice. Equally important are specialists from disciplines not generally encompassed by conventional clinical pharmacologists including anaesthetics, gynaecology and obstetrics, dermatology, paediatrics, psychiatry and primary health care. Without doubt, however, clinical pharmacology has served central government well in relation to its drug regulatory function and has made a singular contribution to the public health.

The future role of clinical pharmacology in UK and European drug regulation is less certain. The next few years will inevitably see significant changes in drug regulation throughout the European Community. Proposals now under discussion envisage the creation of a European Medicines Evaluation Agency which will have responsibility for the assessment of products

*This paper is based on a lecture given at a symposium entitled 'The roles and responsibilities of Clinical Pharmacology' held at the British Pharmacological Society meeting at St George's Hospital on Thursday 18 December 1990

submitted through the proposed 'centralised' system, as well as a role in binding arbitration for other products submitted through the 'decentralised' (i.e. individual member states) system. It is, I believe, imperative that European clinical pharmacologists should play at least as important a part in the future as British clinical pharmacologists have in the past.

## Local government

The responsibility for promoting rational prescribing has, as discussed earlier, now been largely devolved to Regional, District and Family Health Service Authorities.

### *Regional Health Authorities*

Under the NHS Act (1977) Regional Health Authorities have responsibility for the allocation of resources (capital and revenue) to both District and Family Health Service Authorities. Regional Health Authorities are required to oversee the use of funds by District Health Authorities and Family Health Service Authorities in meeting the health needs of their populations, and they are expected to undertake strategic planning of the provision of health care for the region as a whole. In particular, Regional Health Authorities need to develop the means to ensure that their populations receive safe, effective and economic drug therapy. In reviewing its responsibilities, the Northern Regional Health Authority has recognised the importance of an independent and clinically authoritative source of advice, both for itself and for District Health Authorities and Family Health Service Authorities, which draws on a sound professional base. The Regional Health Authority has also been anxious to ensure that the availability of advice was not too closely identified with a Regional hierarchy. In the Northern Region there has been a long tradition of close and effective collaboration between the Regional Drug Information Unit, the Regional Clinical Pharmacology Unit, and the University Department of Clinical Pharmacology. The Northern Regional Health Authority has therefore established a Regional Drug and Therapeutics Centre to discharge its regional responsibilities in relation to effective prescribing and economic drug use. The responsibilities of the Regional Drug and Therapeutics Centre are shown in Table 1. They encompass the traditional activities of the pre-existing Drug Information and Clinical Pharmacology Units (Tasks 2, 5, 6 and 7), but they include major roles in relation to strategic planning (Task 1), monitoring drug use and expenditure (Tasks 3 and 4), and the provision of broad advice to the Regional, District and Family Health Service Authorities (Tasks 8, 9 and 10).

It is apparent that the roles and responsibilities of the Regional and Drug Therapeutics Centre encompass the range and breadth of issues related to drug use and prescribing. It requires the collaborative expertise and skills of pharmacy and medicine generally, as well as particular knowledge and understanding of clinical pharmacology, toxicology, drug information, primary health care, pharmacoepidemiology, and health economics. It especially demands the erosion of narrow and sectarian views of the responsibilities of pharmacists and clinical pharmacologists who comprise the Centre's core staff (Table 2). The Centre is located within the Wolfson Unit of Clinical Pharmacology and is managed by the University of Newcastle upon Tyne on behalf of

**Table 1** Terms of reference of the Northern Regional Drug and Therapeutics Centre

| *Tasks* | *Functions* |
|---|---|
| 1. | Provision of a comprehensive strategy to assist purchasers and providers of care in promoting safe, effective, and economic use of medicinal products in the hospitals and general practices in the Northern Region. |
| 2. | Provision of a comprehensive drug and poisons information service to health care professionals in the Northern Region. |
| 3. | Monitoring of trends in drug usage and expenditure in hospitals and general practices in the Northern Region. |
| 4. | Establishment of an effective methodology for setting and monitoring indicative drug budgets. |
| 5. | Advice and, where appropriate, provision of continuing education in therapeutics and related areas for medical and pharmaceutical staff in the region. |
| 6. | Provision, where appropriate, of drug analytical and clinical pharmacokinetic services to hospitals, Family Health Services Authorities and budget holding general practitioners in the Northern Region. |
| 7. | Monitoring adverse effects of licensed medicinal products in the Northern Region, in collaboration with the Medicines Control Agency. |
| 8. | Identification of medicines-related issues of concern or importance for Health Services in the Northern Region and to formulate advice on them (assisting where appropriate with implementation). |
| 9. | Assistance with the discharge of medicines-related statutory and other functions required of the Regional Health Authority by the Department of Health and other bodies. |
| 10. | Provision of *ad hoc* advice on pharmaceutical and clinical pharmacological/toxicological issues and developments. |

**Table 2** Staffing of the Northern Regional Drug and Therapeutics Centre

| |
|---|
| *Medical directorate* |
| Medical Director |
| Lecturer in Primary Health Care (Therapeutics) |
| Lecturer in Statistics |
| Technical and Clerical Staff |
| *Pharmaceutical directorate* |
| Pharmaceutical Director/Regional Pharmaceutical Adviser |
| Drug Information Services Senior Manager |
| Drug Use Review Senior Manager |
| Supporting Pharmaceutical Staff |
| Clerical Staff |

the Regional Health Authority. The Centre thus has access to the wide range of skills available within a Civic University, its Medical School and the associated teaching hospitals.

The strategy adopted in the Northern Region for the promotion and monitoring of rational drug use is, in principle, comparable with analogous developments in Northern Ireland. It offers very considerable opportunities for clinical pharmacology which Regions and Health Boards in other parts of the country may wish to observe closely. And it presages a role for clinical pharmacologists in the promotion of public health, a subject about which too many of us have, perhaps, been too silent for too long.

*District and Family Health Service Authorities*

The NHS and Community Care Act (1990) gives powers to Health Service Bodies to enter into NHS contracts with District Health Authorities acting as purchasers and Units acting as providers. District Health Authorities continue to have managerial responsibility for those hospitals within their geographical boundaries that are not Self-Governing Trusts. Section 18 of the 1990 Act also places a duty upon Family Health Service Authorities to notify every general practice, annually, of the 'indicative amount' which it believes is reasonable to expect the practice to use in supplying drugs, and listed appliances.

Clinical pharmacologists have had considerable influence, mainly within University Hospitals, in encouraging and stimulating rational drug use. They have been leaders in the formation of hospital and district drug and therapeutic committees. Together with their colleagues in hospital Departments of Pharmacy they have been responsible for the success of local formularies. And, again in collaboration with hospital pharmacists, they have been instrumental in the development and use of systems to monitor drug expenditure.

Clinical pharmacologists (apart for the few who hold appointments in non-teaching hospitals) have had slender influence on District General Hospitals or Primary Health Care. Yet the needs are no less than in teaching hospitals and represent a real challenge for clinical pharmacologists particularly in relation to drug prescribing in the community. Family Health Service Authorities have now appointed Independent Medical Advisers to help, encourage and stimulate local general practitioners to become safer, more effective and more economic prescribers. These Independent Medical Advisers need help, advice and succour. They will depend, to a large extent, on the discipline of clinical pharmacology: and they should be able to expect every assistance from their local (regional) clinical pharmacologists.

## Conclusions

Clinical pharmacologists have played an important role in the delivery of health care both centrally and locally. In promoting rational drug use clinical pharmacologists have too easily seen themselves as 'therapeutic policemen' rather than 'therapeutic referees'.

The future role for clinical pharmacologists is considerable: Regional, District and Family Health Service Authorities all require our special skills and expertise even if some are, as yet, unaware of our potential contributions.