

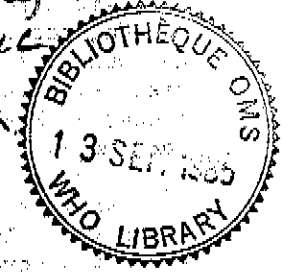


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EDUCATION AND TRAINING FOR THE RATIONAL USE OF DRUGS
 BY HEALTH PERSONNEL AND THE PUBLIC¹

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EDUCATION AND TRAINING FOR THE RATIONAL USE OF DRUGS
BY HEALTH PERSONNEL AND THE PUBLIC

1. The rational use of drugs requires that patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and the community. Rational use implies balancing benefit against risk and cost and is the joint responsibility of policy-makers and drug regulatory authorities, the pharmaceutical industry, health care professionals, and patients and the general public as consumers.

2. Rational drug use concerns equally the developed and the developing countries. In developed countries inappropriate and unnecessary prescribing is placing a severe strain on the health care budget as well as increasing the burden of iatrogenic disease. In developing countries the unnecessary use of inessential medicines and the relatively high cost of many essential ones impedes the delivery of health care (1,2). Irrational drug use is therefore a matter of major concern for all countries.

EDUCATIONAL AND INFORMATION REQUIREMENTS FOR RATIONAL DRUG USE

3. If policy-makers are to formulate coherent strategies to promote rational drug use they require information about their community's pharmaceutical needs, the cost of meeting them, and the utilization of pharmaceutical products. Requirements for essential medicines can be estimated from the prevalence of diseases for which effective drugs are available. An adequate epidemiological data base is therefore an essential prerequisite for planning rational drug use. In developing countries without adequate epidemiological information a service-based or demand-morbidity method can be successfully adopted (3). Projections of drug consumption must also take into account the community's desire for self-medication; policy-makers should draw up realistic self-medication strategies (4).

4. Health care budgets are under severe constraints in both developed and developing countries, and policy-makers therefore need reliable estimates of the cost of medicines. In countries with a substantial indigenous pharmaceutical industry reasonable pharmaceutical price stability can usually be achieved. In countries without a significant national pharmaceutical industry prices may fluctuate widely because of changes in exchange rates or interruptions in supply.

5. Information about drug utilization is as important for developed countries as for less developed ones. Drug utilization data can be used to identify areas of wasteful and unnecessary prescribing, alert policy-makers and regulatory authorities to any increase in iatrogenic disease, and form a basis for monitoring the performance of health care professionals. They can be obtained from the sales figures of individual pharmaceutical companies, the purchases made by pharmacies and hospitals, and analysis of prescriptions. Yet, even where reasonably accurate drug utilization data are available to governments and policy-makers, there is little evidence that appropriate action is taken on them. For example, in developed countries problems associated with dependence on benzodiazepines (5) could have been anticipated by the health authorities during the 1970s when they began to be used widely and excessively (6).

6. In addition to providing policy-makers and administrators with the necessary information for planning the rational use of pharmaceutical resources, there is a need for training them in reaching appropriate decisions. One particular approach, pioneered by WHO in collaboration with the Harvard Business School, has been the use of case histories designed specifically for health administrators in less

developed countries. Extension of this scheme could probably improve the quality of decision-making by health administrators in developed and developing countries.

7. The staff of national drug regulatory authorities have the responsibility of ensuring that pharmaceutical products are of satisfactory quality, effective for the indications claimed by their manufacturers, and safe in relation to their efficacy. The professional and scientific staff of regulatory authorities have backgrounds in pharmacy, medicine, pharmacology, toxicology and statistics. The professional skills required of a member of a regulatory authority, however, are broader than those acquired during conventional training programmes in pharmacy, medicine, or science. In-service training of the professional staff of regulatory authorities in developed and developing countries therefore requires closer attention than it has been given in the past.

8. The inferior quality of some pharmaceutical products, particularly imported generic preparations and drugs manufactured locally, has generated concern in both affluent and poor countries (7,8). Quality assurance and quality control are the responsibility of pharmaceutical assessors in regulatory authorities. The WHO Certification Scheme, which attempts to provide relevant information, does not, however, provide a substitute for proper local control of quality and stability. Quality assurance requires the establishment of an appropriately trained inspectorate. Training schemes for plant inspectors have been arranged by UNIDO. The necessity for quality control laboratories has been accepted in developed countries, but the lack of equipment and trained staff has prevented their establishment in many less developed countries. Facilities for the training of quality control personnel from developing countries have been made available through IFPMA. This training, however, will be of little value if policy-makers do not accept the importance of adequate arrangements for quality assurance and quality control and make appropriate financial provision. Pharmacists in regulatory authorities therefore have the special responsibility of educating policy-makers about the importance of those aspects of drug regulation and of the consequences to public health of any deficiencies.

9. Medical staff in regulatory authorities are responsible for assessing the efficacy and safety of new and marketed pharmaceutical products. In addition to their general medical training, medical assessors also require experience in clinical pharmacology or pharmaceutical medicine. In developed countries the recruitment of appropriately trained individuals has not been easy, in part at least because of the scarcity of clinical pharmacologists outside northern Europe. In developing countries recruitment of appropriately trained medical assessors is often extremely difficult; urgent action is required to provide suitable in-service training for new recruits with previous experience in medical disciplines other than clinical pharmacology. Given the small number of trained clinical pharmacologists in developing countries, local in-service training will often be impracticable. Consideration should therefore be given to establishing training courses on a supranational basis.

10. Assessment of the efficacy and safety of new pharmaceutical products will generally be based on submissions from individual pharmaceutical companies. Proper assessment of animal toxicology findings, clinical trial data, and human safety data demands expertise in a wide range of disciplines as well as knowledge of contemporary medical and scientific literature and good judgement. Information about the pharmacological and toxicological properties of the class to which the preparation belongs should be available to the medical assessor in standard works of reference. Decisions reached by other regulatory authorities may also be relevant.

11. In evaluating the continuing efficacy and safety of marketed products the medical assessor will depend particularly on reports in the medical literature, post-marketing experience gained by other regulatory authorities and, most particularly, post-marketing surveillance in his own country. The medical literature provides an important source of scientific data to support (or refute) further indications for a particular product. It may also provide the first reports (alerts) of suspected adverse reactions (9). Other regulatory authorities may provide additional information about suspected adverse reactions. Every regulatory authority, however, needs its own mechanisms for post-marketing surveillance. Geographical and racial differences in disease patterns, pharmacogenetic polymorphisms, and environmental influences on drug action make it unwise to extrapolate drug safety from one population to another.
12. Medical assessors therefore require information if they are to fulfil their responsibilities adequately. In developed countries library facilities and an informal network of regulatory authorities facilitate information retrieval and exchange. In developing countries limited access to the current medical literature and the absence of an informal information network may be a bar to effective drug regulation. Within national regulatory authorities WHO has contact with nominated information officers who act as recipients for WHO information bulletins containing brief reports of important regulatory decisions and current drug problems. These bulletins should help ensure that medical assessors in regulatory authorities remain in touch with international developments. The suggestion that the WHO newsletter should be issued more frequently and include data sheets on new products from the country of first registration requires further examination (10).
13. Information about the safety of marketed pharmaceutical products requires the establishment of local post-marketing surveillance schemes. The cheapest and simplest system is that of voluntary adverse reaction reporting by prescribers (11). Voluntary reporting systems are capable of detecting new adverse reactions and play an important role in the evaluation of known adverse effects (12). They are relatively easy to establish, requiring only the enthusiasm and goodwill of the health care professions. They do not, at least in their early stages, require computer facilities, and they are appropriate for use in both developed and developing countries.
14. To exercise proper professional judgement in prescribing drugs for their patients, doctors need basic background knowledge and understanding of pharmacology, clinical pharmacology, and therapeutics. They also need accurate information about the properties, benefits, risks, and cost of all the pharmaceutical products available to them for prescribing.
15. Pharmacology is an essential component of the modern undergraduate medical curriculum. There is, however, a large gap between the basic science of pharmacology and its application to practical therapeutics. In northern Europe and Australasia clinical pharmacology has developed both as an academic and as a service discipline to fill this gap; formal instruction in clinical pharmacology has become a permanent feature of the medical curricula in those countries and is an integral component of their qualifying examination systems. Even in the United Kingdom, however, where almost every medical school has established a department or subdepartment of clinical pharmacology, a recent government inquiry into effective prescribing urged that more attention be given to this area (13). Many developed countries and most developing countries have failed to recognize clinical pharmacology as a service specialty and neglected its potential contribution to undergraduate training. Although the impact on rational drug use will be long-term, improved undergraduate education in clinical pharmacology is likely to be one of the most cost-effective ways of improving prescribing.

16. Undergraduate teaching programmes in clinical pharmacology should seek to provide students with a knowledge of the scientific basis of therapeutics. This means instruction in the actions, therapeutic effects, toxicity, and fate of the major drugs. Students should also be taught about the relative importance of various sources of information and be introduced at an early stage to their national formulary. They need to know how to evaluate published claims of efficacy and safety, understand the sociology and economics of prescribing, and be adequately prepared for their role as educators of other health care professionals and patients.

17. Advances in clinical pharmacology and therapeutics and the influx of new pharmaceutical products make it essential for practising doctors to have access to appropriate prescribing information. To prescribe a drug safely and effectively doctors need to know its pharmacological action, the preparations available, and the therapeutic indications for which it is effective. They also need to know the usual range of effective doses, whether dosage titration is necessary, what dosages are recommended for special patient groups (e.g., the young, the elderly, the malnourished), and what monitoring is necessary both during and after treatment. Prescribers must be provided with information about the adverse reactions and interactions that may be encountered, their type and frequency, their relationship to dosage, their prognosis, and their management or prevention. Finally, they need to be aware of the likely effects of the drug if given during pregnancy. This information should be provided by national formularies which, when properly prepared, can play an extremely important role in encouraging rational drug use. They can provide better comparative data on safety and efficacy than the literature of pharmaceutical companies. Publications of pharmaceutical companies (e.g., Data sheet compendium, Physician's desk reference) are potentially useful adjuncts to national formularies in providing prescribing information on individual products. They must, however, be factually accurate and should undergo some form of review to ensure that they are, such as approval by the regulatory authority before they are distributed. Data sheets should contain not only full prescribing information but also details of excipients, and should carry the date of the last review by the regulatory authority.

18. National and local drug bulletins and newsletters are distributed in many developed countries to encourage rational prescribing. These have been produced in response to perceived local or national needs by government health departments, consumer organizations, academic units of clinical pharmacology, and local hospitals. WHO headquarters issues a quarterly Drug Information Bulletin and a number of regional offices issue similar publications. The influence of bulletins and newsletters in encouraging rational drug usage is presumed rather than proven. While it is inherently likely that they have beneficial effects, further work is needed to establish the most appropriate scope, format, and style for different readerships.

19. Meetings, lectures, and seminars on clinical pharmacology and therapeutics are important ways for doctors to maintain their competence as prescribers. In most countries, however, public funding for these educational activities is limited and many such meetings are organized and financed by the pharmaceutical industry. There is a real danger that, by relying on the pharmaceutical industry for the financing of continuing education in rational drug use, policy-makers and health administrators will not achieve overall control of the use of drugs.

20. The traditional role of pharmacists in dispensing prescriptions has become less important with the wide availability of finished pharmaceutical products. They have therefore increasingly become involved in counselling patients about the use of prescribed medicines, advising about medicines for self-medication, and providing other health care professionals (including doctors) with information

about drugs. In developed countries these extensions of the traditional role of the pharmacist have become institutionalized in the subspecialties of clinical pharmacy, ward pharmacy, and information pharmacy. In developed countries there has also been some increase in the range of over-the-counter products that a pharmacist may offer patients, on his own responsibility, for self-medication. These changes have not invariably been accompanied by appropriate changes in the undergraduate education of pharmacists. The training must provide students with the necessary skills and attitudes that will enable them to meet their newer responsibilities.

21. Practising pharmacists also need information about both the pharmaceutical and the clinical aspects of the products they dispense. They require information about quality and stability; they must have available to them the clinical indications that have been accepted by the regulatory authority; they should be aware of a product's important adverse effects and its potential interactions with other drugs; and they must be able to confirm that the prescribed dosages are appropriate. This information should be available in national formularies and pharmacopoeias.

22. Nurses are involved in administering drugs to patients and in counselling them about their safe use. They also have some prescribing responsibilities, although the range varies in different countries.

23. The education of student nurses needs to reflect accurately their responsibilities for promoting rational drug use within the context of their future nursing practice. Moreover, irrespective of the type of health care delivery system within which they will be working, nurses must be adequately prepared for their role as educators and counsellors. They should be able to explain to patients why the medicines they are receiving are necessary, how they should use them most effectively, and how they should undertake self-medication for themselves and their families.

24. Nurses need information about the medicines they administer and prescribe. This information should include the indications, the preparations available, the route(s) of administration, the dosages, and the likely adverse reactions. They also need to know how the drug should be taken in relation to meals. For drugs that they themselves prescribe nurses need additional advice on the duration of treatment regimens, the need for dosage adjustments in special patient groups, and the precautions to be adopted when giving drugs to pregnant women.

25. The format in which information on drug administration and prescribing can be best provided for nurses needs to be tailored to meet their diverse roles and responsibilities. A national formulary is very useful for nurses working in most clinical situations, and formularies should be constructed with the needs of nurses in mind. Additional material may be necessary for midwives and for those working in specialized fields such as cancer, intensive therapy, renal dialysis, and psychiatry. Specially prepared material is also likely to be required by nurses working in rural communities, and by others with responsibilities for supervising community health workers, as well as by those providing contraceptive services.

26. Community health workers (variously described as rural health workers, health guides, barefoot doctors, village health workers, health promoters, health kadars, etc.) are playing an increasingly important part in the delivery of primary health care in developing countries (14). It is the experience of WHO that community health workers can be trained to use a limited number of drugs with skill and judgement. To do this, however, they require appropriate instruction and written information to support their prescribing in practice. To use their limited range of drugs most effectively, community health workers require information on storage,

clinical indications, dosages, precautions, contra-indications, and adverse reactions. They also need adequate training in explaining to patients about the medicines they prescribe and about appropriate self-medication.

27. Consumers in both developed and developing countries have a right to know about the drugs they are prescribed by health care professionals. They also require advice about self-medication. Patients need to know the name of the drug they have been given and the reasons why it has been prescribed (15). They also need to know how to take their medicine, what to do if they forget a dose, for how long the course of treatment is to last, and why it is necessary to continue it even though their symptoms may have disappeared. Patients can also expect advice about the adverse reactions they may encounter while taking the drug; the occurrence of some adverse reactions requires immediate action by the patient, whereas others may disappear with continued administration of the drug. Unless patients are provided with such information they cannot take appropriate action. Patients are unlikely to remember all the information they need during a single consultation and reminders by the dispensing pharmacists are therefore important. The provision of written information, specific for the drug, is probably the most effective way of communicating this essential information (16,17). Policy-makers, health care professionals, and the pharmaceutical industry should be encouraged to provide written information routinely specifically designed for patients (patient package inserts).

28. In those countries in which self-medication is encouraged, or at least accepted, the public needs adequate information about safe and effective self-medication. In these countries the development of an appropriate national self-medication policy is desirable. Regulatory authorities have the same responsibility for ensuring that medicines available for self-medication are safe and that the advertising claims made by their manufacturers are clear, unambiguous, and precise as they have for prescription drugs. Regulatory authorities should also ensure that medicines available for self-medication are labelled with appropriate advice on indications, dosages, warnings, and adverse reactions.

29. Consumers must also have confidence in the ability of health care professionals to use drugs safely and effectively. They can reasonably expect to know that prescribers are adequately trained and have sufficient and appropriate information about the drugs they use.

EDUCATION AND TRAINING FOR RATIONAL DRUG USE

30. Education and training to encourage the rational use of drugs must take into account the historical, cultural, and structural features of society that encourage irrational drug use. Irrational use is historically ancient and geographically universal. The voluminous pharmacopoeias of ancient civilizations (18) demonstrate that man's insatiable appetite for medicines is no recent aberration. Unquestioning faith in the ability of drugs to prevent or cure disease, improve athletic or sexual powers, or provide psychological pleasure, is universal among wealthy urban populations in developed countries as well as the poor in developing countries. This faith renders ordinary people susceptible to the marketing pressures of manufacturers and retailers of medicines and medicinal products. As a result, the promotion of drugs for self-medication (either overtly or covertly) may result in the use of products that are ineffective or dangerous, and may also squander individual financial resources that could be put to better use. The promotion of prescription drugs to the general public occurs in both developed (19) and developing (1) countries, creating a demand for supplies from health care professionals that may be irresistible.

31. Attempts to change public attitudes towards the use of medicines require a concerted approach that has not been seriously attempted in either developed or developing countries. Although health education programmes have tried, with varying degrees of success, to modify behaviour in certain specific areas such as drug abuse, the attempts are unlikely to succeed unless a more fundamental approach is adopted, involving changing public attitudes to the use of drugs for both therapeutic and non-therapeutic purposes. Such an approach to the misuse of drugs needs to be accompanied by a proper understanding of how to use self-medication where that is accepted practice.

32. The paucity of training opportunities in clinical pharmacology for health care professionals, together with exaggerated public expectations of the benefits of drug therapy, has resulted in a vacuum that has to a considerable degree been filled by the pharmaceutical industry in many parts of the world. The sophisticated promotional and information techniques of the pharmaceutical industry could, if appropriately applied, substantially influence public attitudes. The industry rightly claims credit for the discovery and development of many medicinal products that have had a major beneficial impact on health; effective vaccines, anaesthetic agents, and drugs to treat a wide range of microbial, cardiovascular, respiratory, and psychiatric disorders have made a crucial contribution to medical care in developed countries and, to a lesser extent, in developing countries. These positive features, however, have too often been accompanied by over-zealous marketing and promotional techniques that have encouraged the extravagant use of drugs. The exaggerated promotion of medicines among an over-optimistic and unquestioning public and inadequately educated health care professionals leads inevitably to irrational drug use. Measures designed to curb extravagant drug promotion must, however, be accompanied by attempts both to change public attitudes and to increase knowledge amongst health care professionals.

Whose responsibility?

33. The responsibility for promoting the rational use of drugs does not lie with any single group. Policy-makers and health administrators, health care professionals, the pharmaceutical industry, and consumers must all play their part.

34. Identifying the goals of rational drug usage and providing the necessary financial and human resources to achieve them are the responsibility of policy-makers and health administrators. In achieving the goals policy-makers need the advice and support of health care professionals, the pharmaceutical industry, patients, and the public. The potential for conflict, however, is substantial: health care professionals tend to be suspicious of political attempts to interfere with clinical freedom as they perceive it; pharmaceutical companies resent measures which they fear could reduce their profits; patients understandably demand that what they perceive to be the most effective medicines should be available to them, irrespective of cost; and the public desires open and easy access to safe medicinal products for self-medication. The resolution of these conflicts requires great political skill.

35. Policy-makers and health administrators also need to ensure that the training of health care professionals is adequate and that there is a coherent strategy for continuing education. In addition, they should ensure that doctors, pharmacists, and nurses can continually educate themselves by having easy access to reliable sources of unbiased information such as a properly prepared national formulary. In producing national formularies some developing countries may wish to draw on those already available in developed countries, at least in part. However, it is important to recognize that local factors usually require each country to aim at producing its own national formulary. A similar formulary is needed by community health workers, modified to meet their own special needs. Excellent examples have

already been produced by some developing countries (20,21). Policy-makers and regulatory authorities should also be concerned to ensure that prescribing information published by pharmaceutical companies is accurate and complete. The methods by which this is accomplished will vary, but unless the authenticity of the manufacturers' promotional claims is assured rational prescribing will not be possible.

36. The responsibility for ensuring that the information given to health care professionals is accurate and unbiased rests with the regulatory authorities. In fulfilling that responsibility, regulatory authorities need the advice and support of the health care professionals themselves, particularly those with special knowledge and expertise in particular areas of medicine; clinical pharmacologists in hospitals and academic institutions are a particularly valuable source of advice. Health care professionals also have individual and collective responsibility for ensuring correct use of the medicines they prescribe and for the education and counselling of their patients.

37. It is the responsibility of consumers to act on the information they have been given for the safe and effective use of medicines. Consumer organizations in some countries contribute greatly to ensuring that health care professionals have access to unbiased information on therapeutics generally and prescribing in particular and that people have access to such information in a language they can understand. Consumer organizations play an important role in representing the interests of patients and the public at the boundary between politics and medical practice, although in maintaining their independence of vested interests they sometimes come into conflict with policy-makers, regulatory authorities, health care professionals, and the pharmaceutical industry. They are, however, an important ingredient in the social control of health systems, including ensuring the proper use of drugs.

CONCLUSIONS

38. It can be seen that the rational use of drugs in both developed and developing countries requires the cooperation of policy-makers, health administrators, health care professionals, and consumers. For such cooperation to be fruitful, proper understanding of the many factors involved is required by all concerned. Education and training can make a valuable contribution to this understanding. It is the responsibility of individual countries to find the political, financial, and practical means for that purpose.

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