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WHO'S ROLE IN TRAINING, EDUCATION AND OTHER INFORMATION TRANSFER

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WHO'S ROLE IN TRAINING, EDUCATION AND OTHER INFORMATION TRANSFER

The scope of WHO's training activities

1. Self-reliance in virtually every sphere of government activity is built upon sound management and technical competence. Training and education have consequently long been recognized as staple elements in WHO's supportive role to countries concerned to develop their health care infrastructure. These activities have several distinct foci. On the one hand emphasis is placed upon the development of planning and managerial skills as key elements in the elaboration and implementation of national health policies. On the other hand, with a view to extending the coverage of medical care particularly within developing countries, much attention is now directed to establishing primary health care systems and creating a cadre of community health workers. Thirdly, the strengthening of research capability has been accorded priority in selected areas both in an administrative context, as in the planning of health services, and in a technical context, as in the provision of institutional support and the promotion of research programmes of high social relevance.

2. Each of these elements of training and education is represented within WHO's drug-related activities. Over the years training programmes have been developed to subserve and to promote national regulatory capability, the concept of essential drugs particularly in relation to the development of primary health care, and the evolution of clinical pharmacology and epidemiological approaches to drug monitoring as disciplines concerned with the rationalization as well as the advancement of therapeutic management.

The development of national regulatory capability

3. Comprehensive national approaches to drug control are very largely a phenomenon of the post-thalidomide era. In most of the highly developed countries attention was initially directed primarily to the assessment of newly developed products. The review of pre-existing drugs was regarded as a collateral activity, subordinate in importance to preventing the accession of unacceptably hazardous new drugs to the market. Ten years ago few national administrations had compiled comprehensive catalogues of drugs available on their national markets. Many had still to embark upon a systematic review of products marketed prior to the implementation of statutory registration procedures. Even now very few countries have completed this initial survey. Virtually everywhere products can still be found that are promoted on the basis of advertising that has not yet been subjected to control, and the number of countries exploring administrative options for rationalizing the structure of their drug markets is increasing.

4. The regulatory basis of drug control is thus still evolving in developed as well as in developing countries. Indeed, the adequacy of WHO's Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, which was introduced in 1975 as a basis for exchanging information on drugs between governments, is also now frequently called into question.

5. Against this background of evolution and reappraisal and of differing national philosophies and needs, an exclusively didactic approach to training and education in drug regulation at international level would be inappropriate. Over the past five years, therefore, WHO has placed emphasis on providing a forum for discussion of administrative strategies and major technical issues between senior officials from regulatory authorities on a worldwide basis. As a result of a joint initiative by the United States Food and Drug Administration and WHO in 1980, the

biennial International Conference of Drug Regulatory Authorities (ICDRA) has become an influential yet informal mechanism for the exchange of ideas and for upgrading collaboration between national authorities.

6. The support and patronage that the ICDRA receives from many governments of developed and developing countries alike has created a better appreciation on every side of the need for an effective flow of information between national authorities, and it has highlighted both the strengths and the shortcomings of the Certification Scheme. It has given national officials an insight at first hand into how other countries at all levels of development approach their tasks and how they respond to common problems. It is also providing opportunity for an exchange of views on unresolved and innovative aspects of drug control including such varied topics as the labelling of pharmaceutical products, the development of orphan drugs and the impact of recombinant DNA technology on the regulatory process. To ensure that Conference programmes are responsive to regional requirements, a planning meeting is convened in the alternate years in accordance with agreed terms of reference (Annex 1) both in order to settle the agenda for the forthcoming Conference and to follow up the implementation of previous recommendations.

7. Whereas the International Conference is of value to countries wishing to refine or extend their existing regulatory operations, its existence has also underscored the fact that many countries have yet to create a system of drug control appropriate to their particular circumstances. Indeed, the model provided by many highly developed countries - centred, as it is, around multidisciplinary technical assessments of drug safety and performance - may well serve to deter rather than to encourage these authorities from embarking upon a systematic approach to regulation. Many countries are inherently dependent upon externally-generated information in formulating their decisions in this technically complex field. Their prime need is to create an operative framework within which information available internationally can be used to best advantage.

8. Much is already in place to provide the basis of a simplified registration procedure, including the WHO Certification Scheme, the Model List of Essential Drugs, the International Pharmacopoeia, the model quality control laboratory and the technical information generated both by national regulatory authorities and WHO which is circulated through the network of designated national information officers. Work is already in hand within WHO on a manual that describes and interrelates these resources with a view to demonstrating how they can be utilized to develop a simple, yet effective, national registration system which, in turn, might provide the administrative basis for a statutory system of control.

9. Meanwhile, informed advice about the planning and organization of a national control facility has been available to many developing countries on a consultancy basis, both within the context of bilateral collaboration and under the auspices of the WHO Fellowships programme. The Organization has also attracted the collaboration of governments, interested nongovernmental organizations and universities in providing individual or group training in specific aspects of drug control, notably in laboratory management and drug analysis as it relates to quality control, and in drug selection and procurement.

Training in drug quality control and drug assessment

10. Since 1947 WHO has provided fellowships as one means of helping Member States to train selected individuals for responsible positions in health administrations. The financial assistance that is provided enables individuals to follow an advanced programme of study, usually abroad, with the understanding that the nominating governments will employ the returning fellows in appropriate capacities. Whereas a

retrospective study undertaken in one region of WHO¹ suggests that both the value and the subsequent utilization of this training in career development is high, the total number of fellows that can be accepted for training is limited, and the scheme is open to nomination of candidates in every field of health. Thus the proportion of pharmacists contained within the sample of more than 400 fellowships subjected to review was less than 3%.

11. In order to satisfy the demand for training in drug regulation, WHO has consequently needed to seek financial sponsorship from other interested parties including governments, the pharmaceutical industry, professional organizations and universities. Opportunities for using government facilities, including national quality control laboratories for training purposes, are infrequent and at the Thirty-second World Health Assembly in May 1979 the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) made an offer of training places in drug quality control within the pharmaceutical industry. The offer is open to nationals of developing countries employed in governmental control laboratories (not connected with the manufacture of pharmaceuticals) and from pharmaceutical inspection services. Training is directed at individuals who have completed their formal education in pharmacy or chemistry and who have at least a basic knowledge of analytical work. It is carried out in the analytical laboratories or quality control departments of pharmaceutical companies and it is directed, according to individual needs, to chemical, microbiological, or biological control. The training normally extends over a period of 3-6 months with a possibility of more limited training for trainees from countries that are concerned only with dosage forms of pharmaceuticals, and of combined training in all three areas where a demand exists.

12. The companies concerned operate in many countries thereby offering the prospect that training can be carried out in a neighbouring country and efforts are made to tailor the training to individual needs using facilities and equipment available in the applicant's national control laboratory.

13. As of May 1985, 66 applications had been received from 28 countries, half of which are in the African region, and 33 applicants had completed their training. An analogous offer from the World Federation of Proprietary Medicine Manufacturers to train individuals as inspectors of manufacturing premises and distribution facilities is now also under consideration.

14. These arrangements for individual training have long been complemented by shorter periods of group training which provide larger numbers of candidates with an overview of the basics of quality control, and an understanding of how their work relates to the broader responsibility of drug control. A three-week course for 15 to 20 candidates now costs some US\$ 200 000 if it is run on a global basis. Costs are appreciably lower if courses are arranged on a regional or interregional basis, and this also holds advantage in that the course content and the facilities provided are more likely to approximate to candidates' needs and working conditions.

15. Financial and organizational support for these courses has been, and continues to be, generously provided by governments and governmental agencies - notably the Danish International Development Agency and the United States Food and Drug Administration - and by professional organizations including the International Pharmaceutical Federation, the Commonwealth Pharmaceutical Association and - in connection with drug evaluation - by the International Union of Pharmacology.

¹ Lockett B.A. & Truman B.I. A retrospective study of the PAHO fellowships program in the Caribbean, 1970-1979. PAHO Bulletin 1984; 18: 281-287.

Training in drug selection and procurement

16. Teaching and training at country and intercountry level supports the development of national capability to plan, implement, and monitor national essential drugs programmes. WHO's role is best illustrated by examples of past activities and its plans for the future.

17. In the early eighties the Action Programme identified the need for a series of workshops for senior managers and decision-makers. The purpose was to demonstrate actual country experience and to discuss ways and means of improving delivery and use of essential drugs. The workshops have proved useful in exposing participants both to the concepts and the country application of essential drugs but have not aimed at the development of specific skills.

18. WHO has now moved towards supporting a more skills-oriented, "hands-on" type of workshop addressing specific elements of a national essential drugs programme. Examples include drug logistics and distribution, revision of essential drugs lists, drug legislation, quality control, application of microcomputers, and methodologies for estimating national drug requirements.

19. These workshops have and will continue to provide material which can be adapted for use by countries in their own situations. WHO's role thus becomes a supporting one for the development of relevant training material and its dissemination to interested countries.

20. All countries embarking on essential drugs programmes have identified at an early stage the need for training and retraining of health workers in improved diagnosis and patient management. WHO will continue to support national training programmes with training of trainers as well as consultants to assist in the development of appropriate teaching and learning materials. Well tested materials, such as: Managing Drug Supply, Management Sciences for Health, USA; Manual for Rural Health Workers, Ministry of Health, Kenya; Handbook for Health Workers, United Republic of Tanzania; logistics modules, computer software for an essential drugs management system; and methodologies for estimating drug requirements, etc., are now available in several languages.

The development of clinical pharmacology

21. Over the years WHO has repeatedly underscored the potential of clinical pharmacologists to further the socioeconomic implications of drug therapy as well as the innovative aspects. It has defined a role for the specialty in drug usage studies;¹ in promoting the notification of suspected adverse drug reactions in hospital practice;² and in broader aspects of drug control. A series of symposia on clinical pharmacological evaluation in drug control, convened annually since 1972 by the WHO Regional Office for Europe, with sponsorship by the Federal Republic of Germany,³ provides a forum for scientific discussion of clinical issues associated with drug control and with defining a role for the specialty of clinical pharmacology within this context.

¹ WHO Regional Publications European Series No. 8. Studies in Drug Utilization: Methods & Applications. Eds. U. Bergmann, A. Grimsson, A.H.W. Wahba, B. Westerholm. WHO, Copenhagen, 1979.

² International Drug Monitoring. The Role of the Hospital. Report of a WHO Meeting. Technical Report Series 425. WHO, Geneva, 1969.

³ Clinical Pharmacological Evaluation in Drug Control. Annual Reports on a series of European symposia. WHO Regional Office for Europe. Copenhagen. Published annually since 1972.

22. As a more direct service to doctors and scientists working in drug regulation WHO has produced a series of technical reports over the years that provide normative guidelines on the various aspects of drug assessment and much of this material has recently been consolidated in a monograph directed primarily to practising clinical pharmacologists entitled "Safety requirements for the first use of new drugs and diagnostic agents in man",¹

Education

23. Much of WHO's normative technical material is also inherently educational in character. The series of technical reports promulgating the WHO Model List of Essential Drugs² thus provides information that can be used as effectively for training purposes as for the development of national policies and strategies. Moreover, the model drug data sheets that are referred to in these reports - and particularly those for community health workers - are intended primarily as an educational tool.

24. Nonetheless, WHO has not yet clearly defined its mandate in the area of education on the rational use of drugs, and schools of medicine, pharmacy and public health have been slow or reluctant to introduce the concept of essential drugs in their regular teaching programmes. Until a well-designed and well-defined curriculum on the rational use of drugs becomes an integral part of training we cannot reasonably hope for sustained improvement in the use of present and future pharmaceutical products.

25. Successful although limited initiatives have been taken by WHO to introduce the essential drugs concept at least in postgraduate training. Case material illustrating a range of issues on essential drugs has been developed in collaboration with the Harvard School of Public Health, Boston, USA. This material, after testing and use in six to eight schools of public health in both developed and developing countries, will be made generally available.

26. Draft curricula on essential drugs for schools of medicine and schools of pharmacy have also been developed; initial trials in a few institutions will determine to what degree such teaching institutions will be willing and able to introduce in their teaching and research activities these new concepts on the use of drugs.

Information transfer

27. Each of the various systematized approaches developed within WHO for transferring information between national authorities is described in extenso in working paper WHO/CONRAD/WP/1.2. However, a considerable proportion of the technical information provided by WHO to governments on issues concerned with drug safety and drug use is given in response to ad hoc requests.

28. Information transfer has so far been a rather limited activity of the WHO Action Programme on Essential Drugs. It has mainly been restricted to responding to requests for specific information on prices of drugs, suppliers, quality

¹ Safety requirements for the first use of new drugs and diagnostic agents in man. CIOMS/WHO, Geneva, 1983.

² The use of essential drugs. Report of a WHO Expert Committee. Technical Report Series No. 722, WHO, Geneva, 1985.

control, and to general information on essential drug programmes. The Action Programme is planning a more active and targetted approach, initially through the distribution of a newsletter and an information brochure on the Programme.

29. The number and variety of requests that WHO receives from governments for technical information suggests that the time is fast approaching when the compilation and maintenance of a computerized data bank of technical and economic information on drugs, which can be interrogated on-line by all national authorities, will constitute a cost-effective approach to informational needs.

ANNEX 1

ADVISORY GROUP OF REPRESENTATIVES OF DRUG REGULATORY AUTHORITIES

TERMS OF REFERENCE

Objectives

The group will be convened, insofar as budgetary allocations allow:

- during the year preceding each International Conference of Drug Regulatory Authorities and, in any case, at least twelve months before the projected Conference
- immediately on the closure of each Conference.

These meetings will be held with a view to:

- planning Conference agendas and canvassing presentations
- preparing formal reports on Conference proceedings
- monitoring the implementation of Conference decisions
- reviewing implementation of activities concerned with the exchange of information between drug regulatory authorities within the framework of relevant World Health Assembly and United Nations General Assembly resolutions.

Composition

The group will consist of:

- a representative of the host country who will also serve as Chairman
- the immediate past Chairman
- a representative of a national authority within each of the six regions of WHO.

To the extent that is consonant with equitable regional representation, members will be selected having regard to their previous experience of, and contribution to, conference proceedings.

No member shall serve for a period exceeding three years.

One-third of the regional representatives shall be replaced each year. Their successors will be appointed following consultation between WHO headquarters and the interested WHO regional office.

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