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THE ROLE OF THE WHO  
ACTION PROGRAMME ON ESSENTIAL DRUGS AND VACCINES

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## THE ROLE OF THE WHO ACTION PROGRAMME ON ESSENTIAL DRUGS AND VACCINES

Introduction

1. The period following the discovery and development of antibiotics has seen the development of the pharmaceutical industry as it exists today. Numerous new and effective pharmaceutical products have become available and make for a more rational approach to diagnosis and therapy. Tens of thousands of proprietary drugs have appeared on the market in countless combinations of active ingredients.
2. Governments and their drug control authorities have reacted differently to this massive proliferation of pharmaceutical products. The Nordic countries held the number of drugs in their national formularies to some 2000 to 3000, Norway continuing to apply a needs principle it laid down early, admitting new drugs only when medically justified and eliminating older drugs as newer and more effective drugs were submitted for registration. Most industrialized countries, however, in particular those with large pharmaceutical industries, allowed new drugs to enter the market when they satisfied their regulations on quality, safety and efficacy. As many as 5 000 - 10 000 or more prescription drugs appeared on the market, often accompanied by thousands of over-the-counter drugs.
3. Before gaining their independence most developing countries had little access to modern drugs. Now, little attention being paid to public health needs and the economic situation, the demand for drugs in them has escalated and the pharmaceutical industry has marketed ever-increasing numbers of brand-name and combination products. In the 1950s and 1960s developing countries had - and many still have - huge national formularies. Bangladesh had 4000 preparations, Brazil 52 000, Egypt 22 000, Mexico 40 000, Mozambique about 13 000, the Philippines 15 000, Thailand 25 000. (For comparison, the United Kingdom had about 17 000, while Norway had no more than 1900 formulations of about 900 specific chemical entities.) National drug bills soared, often consuming 20%-40% of the meagre national health budgets in developing countries.
4. Paradoxically, in spite of the huge number of different proprietary drugs, there were insufficient basic drugs at prices that the rural and urban poor could afford. The private sector catered, as it still does, to an urban elite, while government health services fought an uphill struggle against the weaknesses of their inherited drug procurement, storage, and distribution infrastructure.
5. A few developing countries (Afghanistan, Pakistan, Papua New Guinea, Sri Lanka, and others) made serious attempts to remedy the situation, but most attempts failed for lack of political will and internal or external pressure, or both. Some countries, however, adopted limited drug lists and reported good acceptance as well as favourable medical and economic results. In the developed countries many hospitals started to experiment with restricted formularies.
6. It was in response to this situation that the Director-General of WHO, in a report to the Twenty-eighth World Health Assembly in 1975, reviewed the main drug problems facing the developing countries and outlined possible new drug policies.

The WHO model list of essential drugs

7. A WHO expert committee met in 1977<sup>1</sup> to answer the pressing question of which basic drugs are necessary for the health needs of a population. It established

<sup>1</sup> WHO Technical Report Series, 1977, No. 615.

guidelines and criteria for the establishment of lists of essential drugs and vaccines. The most important were:

(a) the selection of the drugs should be unbiased and be based on the best available scientific information, yet allow for variations to take local needs and requirements into account

(b) the selection should be based on the results of benefit and safety evaluations obtained in controlled clinical trials and/or epidemiological studies

(c) international nonproprietary (generic) names for drugs or pharmaceutical substances should be used whenever available

(d) in cost comparisons between drugs the cost of the total treatment and not only the unit cost must be considered, as well as the cost of non-pharmaceutical therapeutic modalities

(e) consideration should be given to the competence of the personnel to make a correct diagnosis

(f) when several drugs are available for the same purpose, the pharmaceutical product and dosage form should be selected that provide the greatest benefit in relation to risk

(g) When two or more drugs are therapeutically equivalent, preference should be given to:

(i) the drug that has been most thoroughly investigated

(ii) the drug with the most favourable pharmacokinetic properties, e.g., one that improves compliance and minimizes risk to health

(iii) the drug for which reliable local pharmaceutical manufacturing facilities exist

(iv) the drug and dosage form with the greatest stability or for which adequate storage facilities exist

(h) Fixed-ratio combinations should be accepted only if the following criteria are met:<sup>1</sup>

(i) clinical literature justifies the concomitant use of more than one drug

(ii) the therapeutic effect is greater than the sum of the effect of each drug separately

(iii) the cost of the combination product is less than the sum of the cost of the individual products

(iv) patient compliance is improved

(v) sufficient drug ratios are provided to permit dosage adjustments to meet the needs of the majority of the population.

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<sup>1</sup> More than one-third of all new products introduced worldwide in 1978 were fixed-ratio preparations (Drugs bulletin, No. 2, 34-46).

8. The expert committee in its 1977 report listed as a model about 220 drugs, vaccines, diagnostic agents, and solutions in 26 major categories. The establishment of a WHO model list does not imply that no other drugs are useful but simply that, in a given situation, these drugs are those most needed for the health care of the majority of the population and those, therefore, that should be available at all times in adequate amounts and in the proper dosage forms.

9. The 1977 model list of essential drugs has stood the test of time. It met with initial surprise and resistance from both the medical establishment and the pharmaceutical industry, but it has since gained guarded acceptance from both. The list has been revised three times since 1977 but with only a limited number of additions, changes, and deletions. Given the global investment in research and development for new drugs, it is surprising, disconcerting even, that so few new chemical entities have been added to the list.

#### Action programme on essential drugs and vaccines

10. After the establishment of the 1977 WHO model list of essential drugs, many developing, but no industrialized, countries made attempts to establish national lists suited to their own needs. Today the number of countries with lists of essential drugs or national formularies containing chiefly essential drugs exceeds 80.

11. The establishment of a national list, however, does not necessarily lead to implementation of the concept of essential drugs. In some developing countries the new list of essential drugs became just another list added to the many existing lists. The importation, distribution, and use of expensive non-essential drugs continued as before in the growing private sector and the drugs appeared in the national formularies. In other countries (Afghanistan, Kenya, Mozambique, Tanzania, etc.) the list was applied with some vigour to the primary health care system or (Peru) to reimbursable social insurance schemes. From 1977 to 1982 WHO collaborated in about 30 country studies with a view to analysing the drug supply situation and drug policy and management.

12. The WHO Action Programme on Essential Drugs was formally established in 1981 as an operational programme to support countries in the establishment of essential drug policies. Its aim is to help assure the regular availability of essential drugs of good quality and at the lowest possible prices. In 1981 WHO also joined forces with UNICEF to support the provision of essential drugs for primary health care in developing countries.

13. No more than modest progress was reported by the Action Programme in 1982, only a few countries having formulated national drug policies. In fact, populations that had gone unserved with essential drugs before 1977 continued to go unserved, populations that numbered - and still number - tens, if not hundreds, of millions. To remedy this deplorable situation and accelerate a hitherto slow-moving process, a global strategy that could be applied in Member States was needed. A plan of action was presented in 1982 to the Thirty-fifth World Health Assembly, which endorsed it and its principles. It contained the following major components:

- (a) identifying therapeutic needs
- (b) selecting essential drugs
- (c) estimating the quantities needed

- (d) improving the drug supply system
- (e) ensuring the proper use of essential drugs
- (f) providing the public with information and education
- (g) achieving local production or formulation wherever technically and economically feasible
- (h) ensuring quality control
- (i) monitoring adverse reactions
- (j) introducing appropriate legislation
- (k) meeting manpower requirements
- (l) ensuring coordinated multisectoral action
- (m) establishing monitoring and evaluation procedures.

14. According to the plan, WHO has two mutually supporting roles: coordination and technical cooperation. It is exercising that dual role on the basis of a well-consolidated plan of action and on a policy and strategy that have been proved to be intrinsically sound and economically feasible for most developing countries, with or without international support.

15. Much progress has been achieved since 1982 at the global, regional and country level, as reported to the Health Assembly in 1984.

#### WHO's coordinating role

16. WHO is now recognized as the lead agency in essential drugs. It coordinates, directly or indirectly, international efforts in support of country programmes. Most development agencies in the health field have officially adopted the concept of essential drugs or apply it in practice in support of primary health care. Nongovernmental agencies such as the League of Red Cross Societies have officially adopted the concept. The International Organization of Consumer Unions and its informal network, Health Action International, are strong and often vocal advocates of an essential drugs policy for both developing and developed countries.

17. UNICEF has widespread operational activities in most developing countries, not least in distribution and training, making it an obvious partner for the WHO Action Programme on Essential Drugs and Vaccines. WHO and UNICEF work closely together in countries, and at regional and global levels. UNICEF concentrates mainly on procurement, kit-packaging, distribution and, in some countries, technical support to programme development, while WHO's role consists of programme development, coordination, monitoring, and evaluation, as well as technical and scientific support to countries and international organizations. Both WHO and UNICEF actively mobilize resources on behalf of national essential drug programmes.

18. UNIDO supports technology transfer for the local production of essential drugs and has developed an inventory of suppliers of 26 different raw materials for the formulation of essential drugs. UNHCR has developed a system of essential drug supplies applicable to refugee situations. UNCTAD and the United Nations Office of Transnational Corporations have devoted several studies to the global pharmaceutical situation in relation to pricing, transfer of technology, local

production, patents, etc. The World Bank supports an essential drugs component for primary health care programmes in several countries.

19. The technology-based pharmaceutical industry cooperates with both WHO and UNICEF in commercial transactions with least developed countries for the supply of low-cost essential drugs. Several industry associations and groups of drug companies support training in quality control, distribution systems, and the supply of essential drugs for developing countries. Numerous generic manufacturers, as well as generic subsidiaries of multinational companies, supply essential drugs at low prices and of good quality via UNICEF or directly to developing countries.

20. The advocacy role of the Action Programme has led to wide, although perhaps not yet sufficiently wide, knowledge of the concept of essential drugs. In addition to WHO's official publications on this subject, an ever-increasing literature deals with a range of issues on the production, pricing, marketing, advertising, prescription and use of drugs. More than 250 documents and papers are listed in the Action Programme's annotated bibliography. Numerous TV films, slide shows, newspaper articles, and public debates have highlighted the advantages of an essential drugs policy. The Action Programme is now issuing a newsletter and a brochure on the progress and components of the programme. These are intended to reach wider audiences in both the developed and the developing countries. Seminars, workshops and international conferences aimed at reaching both present and future decision-makers and providers of health care are continuous features of the programme.

21. Financial, political, and technical support has been mobilized and WHO continues to play a strong role in mobilizing support for national essential drugs programmes.

22. The Action Programme stores and distributes a wide range of documents: teaching and learning material for schools of medicine, pharmacy and public health; guidelines, manuals, and therapeutic guides; principles of drug legislation; price lists and names of suppliers of essential drugs; documents on experience in countries and evaluation procedures and reports. Draft drug information sheets are available for adaptation to needs in countries. Most documents are available in more than one language.

23. With the acceleration of national essential drugs programmes, it is envisaged that the WHO coordinating and advocacy role will increase in the coming years. It serves to align policies and strategies so as to facilitate the implementation at the country level of internationally agreed approaches to improving the supply and use of essential drugs. It serves countries directly in the application and adaptation of global policies and strategies to national needs.

#### The technical cooperation role

24. The technical support role to countries now takes up most of the Action Programme's manpower and financial resources. With increased experience, WHO has moved from an initial rather orthodox approach, advocating policy formulation, legislation, quality control, planning, and implementation, to a more flexible pragmatic approach to problems taken if possible in order of priority.

25. Most existing national drug legislation permits initial experiment with essential drug lists, distribution and training and later expansion into primary health care coverage with a national essential drugs programme. Policy formulation can evolve as experience is gained and legislation be drafted and adopted according to needs. It makes little or no sense to establish a more rational drug

procurement scheme if the distribution infrastructure is a major constraint. Training in better patient management may prove futile if drugs are not actually available. A well-developed implementation plan may quickly be shelved if financing is the overwhelming problem. Technical collaboration on essential drugs now focuses on the fastest possible approach to overcoming the major problems, but always with a view to an eventual consolidated national policy and system of selection, procurement, storage, distribution, training, and use of essential drugs. The project approach has long since been abandoned and a national programme approach is systematically advocated. Isolated projects, however well designed and well executed, tend to fizzle out when they ignore the wider context in which they operate; too many pilot projects move from initial enthusiasm to complete abandonment because they have never formed part of an overall policy and strategy.

26. Global guidelines, manuals, etc. take second place to nationally developed material. This can be shared with other countries and can often be adapted to their specific needs.

#### National lists of essential drugs

27. WHO collaborates with national drug committees both in the establishment and revision of essential drug lists and in the selection of lists appropriate for different levels of health care. The WHO model list with its 220 drugs and vaccines has proved to be a most useful tool for national drug committees in establishing their own lists. Few countries have less than that number. Several countries operate national lists with 300-400 different generic drugs.

28. For the different levels in the health care system a surprisingly uniform pattern has been evolving, with about 6-12 drugs at the village level, 15-20 at the dispensary level, and 40-45 at the health centre level. District hospitals need about 100-120, specialist hospitals rarely more than 250 different drugs and vaccines. Many hospital formularies in developed countries satisfy the needs of sophisticated medical care with some 400 different drugs. A recent study in the United Kingdom has demonstrated the positive results of using a limited formulary in general practice: a diverse group of general practitioners showed over a one-year period that a formulary with only 137 drugs could provide adequate treatment for 90% of general practice patients.<sup>1</sup>

29. In its collaboration with countries WHO advises a phased reduction in the number of drugs and a gradual change to generic drug procurement and prescription. Objective information on drugs and, in particular, fixed-ratio combinations that are harmful, dangerous, or without proven therapeutic value is available in WHO and in many drug regulatory agencies in developed countries. This information can assist developing countries to determine which drugs should be removed from the market. The Bangladesh Drugs (Control) Ordinance 1982 took such an approach and removed more than 1500 inappropriate products from the market in a very short period of time. A reduction in the number of drugs after careful selection of essential drugs provides initial and lasting advantages in procurement, storage, quality control, and distribution.

30. Quantification of drug needs poses a far more complex problem than the selection of drugs. It is frequently based on past consumption rather than on present and anticipated morbidity patterns, attendance rates, and the diagnostic competence of the health staff. Since past consumption is an aggregate reflection of numerous and often irrational factors, it is a poor basis for forecasting requirements. This is clear in many developing countries; some drugs are far in

<sup>1</sup> Lancet, 1:1030 (1985).

excess of what can or should be used before the date of expiry, while others are in short supply.

31. The Action Programme has collaborated with several countries in the quantification of drug needs at the primary health care level. A reasonable degree of accuracy has been achieved over a number of years, wastage has been reduced, smaller inventories can be drawn up, and drugs can be used within less than 6-12 months after the date of manufacture. A methodology for projecting estimates of national essential drugs needs has been developed, based fundamentally on morbidity patterns and health services statistics. It is being field-tested in a number of countries, and training in its application will start in 1986 for national health authorities concerned with drug procurement and supply. With successful application, it is expected that considerable savings can be achieved and supply and needs be better balanced. However, operational research may be required in each country to determine the morbidity, attendance rates, skill levels, and the relation of demand to need.

#### National legislation

32. Most developing countries have inherited their drug legislation from the colonial period. It was in principle designed for a completely different socioeconomic and health situation and has proved ill suited to the present public health situation. Many countries have revised and updated, but few have radically overhauled, their legislation. A few bigger countries (India and Mexico) have enacted radical and progressive legislation only to end up in protracted and complex court battles. A few other countries have achieved legislative reform that has had a profound effect on the pharmaceutical sector (Bangladesh, the Gambia, Iran, and Mozambique).

33. Although essential drugs programmes can be implemented without elaborate legislative reform, most countries must face the hard challenge of bringing about such reform. There is no substitute for national efforts to create the legal basis for a drug sector that is suited to the particular needs and circumstances of the country. WHO provides guidelines for such national legislation. The Action Programme has collaborated in the drafting of national legislation and can provide technical and legal expertise to countries that wish to benefit from experience elsewhere.

#### Financial and economic issues

34. People, particularly in rural areas, in many countries have little or no access to reasonably priced drugs. Paradoxically, the government policy of providing free health services, including drugs, has often resulted in no drugs being available in government health facilities, especially in rural areas, leaving the private sector as the sole source. The cost of the drugs is often prohibitive, especially when added to the time and effort necessary to travel to where drugs can be purchased. Thus people delay seeking care until the situation deteriorates into an emergency, when they are obliged to pay whatever the price demanded for drugs.

35. With the implementation of an essential drugs programme drugs can become more accessible, both financially and geographically, to even the poorest income groups. The share of a family's income devoted to the purchase of drugs should remain the same or even decline, thereby freeing income for other purposes. Most importantly, when drugs are both reasonably priced and available people are usually willing to bear some or all of the cost.

36. While the implementation of an essential drugs programme cannot solve a country's foreign exchange problem, it can help to reduce it to manageable proportions as far as drug purchases are concerned. This is achieved by careful estimation of drug requirements, improved procurement, better prescribing, better consumption habits, and so on. Most countries are spending at least \$1 per capita on drug imports, which has been shown to be sufficient to supply essential drugs in primary health care. In Kenya the cost of drugs per outpatient visit to a health centre was only \$0.19, and at a dispensary only \$0.29. In fact, following the implementation of the essential drugs programme (1980-1984), Kenya's total drug bill increased by only 1.2% taking inflation into account, despite the fact that the population increased by over 20% during that period. Yet drugs are now widely available in rural health facilities. This is partly explained by the fact that losses on the way from the central store to consumers were reduced from around 25% to an estimated 5% through the implementation of a strict control system using ration kits and other control measures.
37. Once people are confident that drugs are available the attendance may increase at health facilities and the overall cost per patient will decline with more efficient use of existing personnel and facilities. In both Kenya and Tanzania it appears that attendance may indeed have increased. Another benefit is that people who come to the health facilities for curative care can then be reached by preventive health measures and health education, provided that the health personnel are trained to take advantage of the opportunity.
38. A number of less tangible benefits with economic implications can be expected. Patients have greater confidence in health care providers and in the health care system as a whole. This in turn improves the morale and productivity of the health personnel at all levels and they are better able to meet the expectations of the community. And the availability of essential drugs should go a long way towards improving health in general, to the economic benefit of the community.
39. Experience in Kenya and Tanzania has shown that the cost of implementing an essential drugs programme can be relatively low. The main cost element is the purchase of drugs. Others include the training of health workers, the storage and distribution of the drugs, monitoring and evaluation, and staff costs.
40. A major question is the maintenance of an essential drugs programme. Not only are the populations of most developing countries increasing at 2.5-4% annually but the health budgets have also been stagnant or even decreasing in real terms over the past five years. Clearly many countries may not be able to continue to finance essential drug programmes in a system of free access to health care. One solution to this dilemma is some form of cost recovery. People in virtually all parts of the world have demonstrated their willingness to pay for drugs, even where drugs and health services are supposed to be provided free. In fact, in many countries with government health services private purchases of drugs are twice those of the government. Costs can be recovered in many different ways to fit the economic and cultural circumstances of a country, and selectively either as direct payment for drugs received or as part of a fee for service. Subsidies can be used to make the more expensive essential drugs affordable. Many different options are available for the recovery of costs.
41. Once funds have been recovered from the sale of drugs one problem arising is how they can be used to replenish the stock of drugs. Another is that in many countries the local currency recovered through cost recovery schemes cannot easily be converted into the foreign exchange needed to import drugs. One solution to the first problem that has had some success in several countries is a revolving drug fund. The principle is relatively simple: after an initial amount of capital or

stock of drugs is provided (often by an external donor) the funds are collected and deposited in the revolving fund, which in turn is used to replenish the stock of drugs on a regular basis. A manual on drug supply management published by WHO and Management Sciences for Health,<sup>1</sup> a consulting group, points out, however, a number of pitfalls in the operation of revolving funds: underestimation of the initial stock; unanticipated price increases (although prices of many essential drugs have been declining in recent years, local inflation or exchange rate fluctuations may nullify the decreases); rapid programme expansion; prices fixed too low to recover costs; failure to collect established fees; and theft and other losses. It is important to note, however, that all of these possibilities can be planned for and minimized, if not entirely eliminated.

42. The main obstacle in many countries to the successful implementation of a cost recovery scheme is the shortage of foreign exchange. Unfortunately there is no easy solution to this problem. However, the implementation of an essential drugs programme should reduce to a minimum the need for foreign exchange for drug purchases, and in many cases the amount needed will be below what is currently spent on drugs. A ministry of health that has done all it can to reduce its need for foreign exchange by implementing an essential drugs programme should receive a sympathetic hearing from a ministry of finance or central bank in its request for foreign exchange for drugs. Typically the amount requested represents a relatively tiny percentage of the country's need for foreign exchange - and drugs are surely at least as essential as petrol.

#### Procurement and prices of essential drugs

43. Analysis of prices demonstrates all too clearly that many developing countries, particularly the less populous LDCs, have been singularly unsuccessful in obtaining good quality generic essential drugs at prevailing international prices. Many countries year in and year out pay from three to ten times too much for drugs. Fragmented procurement, poor payment records, complicated specifications, and irrational tendering or ordering systems are among the main reasons for this unacceptable situation.

44. The WHO Action Programme, in close cooperation with the UNICEF Packing and Assembly Centre (UNIPAC), collaborates with countries to improve procurement procedures. Tender documents, price lists, and names of reputable suppliers are available on request. UNIPAC has expanded its procurement activities and, through international competitive bidding for standardized essential drugs, has managed to achieve considerable reductions in the prices of about 140 essential drugs. Countries can obtain essential drugs at these low prices through a reimbursable scheme which, however, requires prepayment in hard currency. A financing arrangement is being developed whereby countries with essential drugs programmes will be provided with credit for drug procurement. In some instances local currency may be accepted in part payment.

45. With the objective of obtaining the lowest possible prices for good quality generic drugs, WHO will continue to work with UNICEF/UNIPAC to procure drugs in sufficiently large quantities to establish reference prices for commodity generic drugs. The prices will be monitored and supplied on a regular basis to countries that need price and market information for their own procurement system.

46. Pooled procurement schemes between countries, particularly smaller countries, provide obvious advantages in terms of economies of scale. However, practical difficulties have so far prevented such schemes from materializing. Several

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<sup>1</sup> Managing Drug Supply, Management Sciences for Health, Boston, 1981.

countries do pool their national requirements to obtain good prices, and the Action Programme advocates this approach for most situations.

#### Local production and formulation

47. Self-sufficiency or self-reliance in the supply of the most important drugs is a declared goal in many developing countries. In fact, however, no country in the world has achieved complete self-sufficiency; even industrialized countries with large pharmaceutical industries rely in part on the importation of raw materials and intermediate and finished products. A number of large developing countries (notably Argentina, Brazil, China, Egypt, India, and Mexico) have gradually built up drug industries, including the production of good-quality raw materials. Often subsidiaries of multinational companies and indigenous factories combine.

48. Many less developed countries have experienced prolonged difficulties in establishing an economically viable local industry. In the absence of supporting industries (packing material, labels, starch, sugar, etc.), the value added component in the formulation of essential drugs is rather small and the technology required to produce good quality products complicated. Smaller quantities of raw material cannot always be procured at a good price and local taxes may add to the cost of the finished product. Irregular power and water supplies, periodic shortages of necessary ingredients, the breakdown of machinery, and competition from imported finished products often lead to low plant utilization. In several LDCs a 20-40% capacity utilization is the rule rather than the exception, so that domestic prices exceed international competitive prices and state subsidies are needed to ensure marketing at reasonably fair prices.

49. Packaging from bulk drugs and the production of intravenous solutions and water for injection may provide a sound first step with a potentially reasonable capital return. More than 40 developing countries formulate part of their requirements for oral rehydration salts at or close to international price levels. With increased experience and knowhow a gradual increase in their activities can be considered.

50. UNIDO is the United Nations agency entrusted with technology transfer in the pharmaceutical area. It has supported a number of developing countries and has increasingly gained experience in this field.

51. It is generally accepted today that the establishment of formulation plants to produce essential drugs at competitive prices requires careful study of technical and economic feasibility.

#### Storage and distribution

52. Problems of storage and distribution are more easily identified than solutions are. Inappropriate buildings, insufficiency or absence of shelf space to store drugs and equipment, lack of staff trained in modern storage and distribution management, shortage of fuel, poor roads, long distances to health care facilities, etc. often appear to be insurmountable obstacles, leading to waste and frustration.

53. Experience in a few countries has, however, showed that it is possible to improve both storage and distribution. Essential drugs are, in fact, reaching the most distant units in several countries on a regular basis and with a minimum of wastage. The ration kit system used in Kenya and Tanzania appears to be a feasible approach. Drug quantities tailored to the needs of a health unit and designed for a specific number of patients are prepacked in sealed boxes. New kits are supplied

on the basis of attendance rates rather than on monthly or quarterly schedules that ignore the number of patients treated.

54. Kit packaging adds to the cost of procurement because of the packing material and labour needed. The additional cost appears, however, to be more than offset by the reduction in wastage and diversion of drugs.

55. The Action Programme, together with UNICEF, collaborates with several countries in improving storage and distribution systems and training store managers in better techniques. Manuals and teaching material on storage and logistics have been developed and the first few workshops have taken place. WHO will continue to collaborate with countries in the improvement of storage and distribution as part of national essential drugs programmes.

56. Research to determine the stability of drugs stored under tropical conditions is under way. Operational research is planned to devise better packaging and presentation forms for the individual patient in the public health sector.

#### Quality control

57. The question is often raised of the quality and quality control of imported or locally manufactured drugs. The degree and extent of the problem are unknown; the evidence ranges from the purely anecdotal to actual demonstration of substandard drug supplies. Clearly governments need to take steps to ensure the quality of all drugs marketed in their country, in both the public and the private sector. WHO provides guidelines for good manufacturing practices and quality control laboratories, including testing methodologies; it also provides technical support and training in quality control.

58. In the absence of a national quality control laboratory and a supporting inspection and enforcement system, countries can nevertheless take important steps to assure good drug quality. Selection of reputable manufacturers is the most important first step to ensuring the continuous supply of good quality products. In addition, countries can insist on assurance of quality through the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (Working Paper 2.6). WHO also provides for the testing of samples at independent collaborating quality control laboratories.

59. Another problem is how to assure the quality of drugs actually supplied to the patient. No tests or certification schemes can prevent the gradual deterioration of products passing through a storage and distribution system and subjected to prolonged heat, humidity, rough handling and careless dispensing. Tropical packing material, careful ordering, and a fast first in first out storage and distribution system can go a long way towards ensuring the arrival of freshly produced products, as has been recently demonstrated in both Kenya and Tanzania. A systems approach is advocated including in-service training of the staff actually handling drugs all the way from the producer to the consumer.

#### Training, education, and other information transfer

60. Training at various levels, education, and information transfer are integral components of the WHO Action Programme in support of national programmes. They are dealt with more specifically in Working Papers 1.2, 3.1, and 3.2.

### Monitoring and evaluation

61. Essential drug programmes, like other programmes, need monitoring to provide decision makers and managers with information to determine to what degree approaches and activities contribute towards the achievement of stated targets. Financial control is needed to keep within budgetary limits and to ensure that cost effectiveness is maintained. Since national essential drugs programmes are relatively recent, it is not surprising that problems have arisen in the monitoring of programme progress. A methodology based on the experience so far gained is currently being developed by the Action Programme in collaboration with a university centre.

62. Two national essential drug programmes in primary health care have now been evaluated. Evaluation procedures and manuals are available from the Action Programme. They can be used to evaluate essential drug programmes and be applied to present supply systems as part of a process for the development of new approaches.

### Conclusion

63. The WHO Action Programme on Essential Drugs has over the few years of its existence emerged as a means of improving not only the availability but also the rational use of essential drugs. In less than a decade it has moved from drawing up a model list of essential drugs towards working systematically on the complex range of issues that every country must address to ensure both the supply and the correct use of good quality medicines. Its implementation by countries constitutes a most important approach towards the rational use of drugs at all levels of health care. It has so far mainly tackled problems in the public sector, with emphasis on primary health care. In countries with a large public sector, it may, with time, demonstrate the feasibility of changing existing patterns of drug use to achieve a more rational use of drugs. In countries with a large private sector the problem of excessive use of drugs is likely to continue or worsen unless concerted action is taken to remedy the situation.

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