



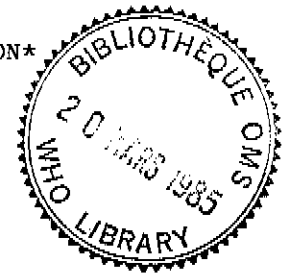
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THE ESSENTIAL DRUGS CONCEPT AND ITS IMPLEMENTATION\*

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1. INTRODUCTION

Drugs play an important role in protecting, maintaining, and restoring health. In the developed countries, the availability of drugs is not necessarily governed by public health needs, rather by supply and demand. The worldwide sales of pharmaceutical products in 1983 is estimated at US\$ 70 billion and are expected to grow to US\$ 127 billion by 1987 (1). The three-quarters of the world's population living in developing countries use only about 15 percent of the world's drug products. The financial resources in these countries are inadequate to meet even the basic requirements of the majority of the population. The discrepancy between need and availability in many of the developing countries has become critical with regard to essential drugs. Ways to narrow this gap are reflected in Resolution WHA28.66 (2) of the Twenty-eight World Health Assembly in 1975 in which the who Director-General is requested: "To develop means by which the Organization can be of greater direct assistance to Member States in advising on the selection and procurement, at reasonable cost, of essential drugs of established quality corresponding to their national health needs". With this Resolution, now eight years old, who entered the era of essential drugs which culminated in the first model list of essential drugs in 1977 and subsequent revisions and updatings in 1979 and 1982 and the establishment in 1981 of the who Action Programme on Essential Drugs.

The provision of essential drugs and vaccines forms one of the basic components of primary health care, expressed in the Declaration of Alma Ata at the who/UNICEF-sponsored international conference on primary health care in 1978. The regular supply of a limited number of essential drugs is also one of the indicators to measure progress in attaining the goal of Health for All by the Year 2000.

2. THE ESSENTIAL DRUGS CONCEPT

In the early seventies, more and more complaints were voiced by health administrators and policymakers of developing countries about too high a proportion of the health care budget (sometimes more than 25%) being spent on drugs. In spite of this, a vast majority of the people living in rural areas had

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and have no access to the most essential drugs. Why? One of the reasons for this unacceptable situation is that the selection of drugs for a country's health services often has been done arbitrarily with no links between drugs and health needs. Many non-essential medicines have been and still are imported and paid for with scarce foreign exchange. Another reason is that hospitals, particularly urban ones, consume much too large a proportion of the national drug bill compared to health centers and dispensaries, which have to face constant shortage or lack of medicines. Furthermore, distribution systems are insufficient, manpower is lacking or is not properly trained to prescribe and use drugs due to inadequate exposure to objective drug information. A comprehensive national drug policy in support of primary health care based upon a selected number of essential drugs is missing in most developing countries. It is against this background that the concept of essential drugs was born.

The gap between developed and developing countries in production and trade in pharmaceutical products also creates, in most developing countries, ever-increasing technical, financial, and social problems. The less developed countries, which have a Gross National Product (GNP) of around US\$ 200 per capita/per year, cannot afford certain essential products at prices which are equal to and even higher than those in developed countries. In most cases, these must also be paid for in the scarce convertible currencies.

The pharmaceutical industry is unique in the scope and depth of its operations in international markets. Integrated pharmaceutical manufacture is concentrated in a few industrialized countries where processes and products are protected by patents, trade names, and know-how. Pharmaceutical technology, including research and development, requires considerable skills, capital, and access to relevant information sources. Price setting on raw materials, intermediate products, and finished drugs are rarely based only on costs. They are also based on market considerations. The proliferation of different drug names and presentations of the same active substance, the use of transfer pricing, and price discrimination make it difficult for developing countries to procure essential drugs rationally.

### *2.1. History*

In 1975 in his Report to the Twenty-eight World Health Assembly (3), the who Director-General reviewed the main drug problems facing the developing countries and outlined possible new drug policies. He also referred to the experience gained in some countries where schemes of basic or essential drugs have been implemented. Such schemes were intended to extend the accessibility of drugs by selecting essential drugs corresponding to health needs, with particular emphasis on primary health care coverage.

Based upon the already-mentioned Resolution WHA28.66 following the Director-General's report, who collected information on selected drug lists from all over the world. Two consultants of who then prepared a working document which (a) *outlined the role of lists* of recommended drugs, (b) *defined terms*, such as basic or essential drugs, drug policy (indicating how a general health care policy is reflected in the drug market), drug economy and drug evaluation, (c) *proposed criteria* of drug selection, and (d) included a *preliminary draft list* of drugs which gave *references* to sources used in the preparation of the list.

This working document was circulated for comments; and in October 1976, an informal consultation of seven participants was convened in Geneva to advise the Director-General on the selection of essential drugs corresponding to health needs, keeping in mind the situation of developing countries where the main objective was to extend the primary health care coverage of the population. In early 1977 the report of this consultation (4), including an annotated list of essential drugs (under generic names), was sent for comments and suggestions to who technical units, to members of the who Expert Advisory Panels on Drug Evaluation and on the International Pharmacopoeia and Pharmaceutical Preparations, to the six who Regional Offices, to Ministries of Health in each region, and to nongovernmental organizations in official relations with who. Seventy-two answers from fifty-one countries were received. Accompanying their answers to who, fifteen persons also submitted different selected drug lists prepared in their own countries at various levels of health care.

The consensus of the comments was that any final list should be the responsibility of local authorities. The drugs in the annotated list had been marked with either Symbol I or Symbol II indicating that they were intended for use at primary level (e.g., health centers, dispensaries) and secondary level (hospitals and specialists). But questions were raised on the practicality of this division - levels of health care and education of health care workers differing considerably among countries. Suggestions were made to abandon categories I and II (also done in First Expert Committee Report), and the importance of well-established criteria to guide in local selection was stressed. Education of physicians and the public through a system of information was also emphasized.

Many answers gave specific comments on drugs and drug groups. Suggestions were made not to exclude antihistamines, cytostatics, cathartics, laxatives, vitamins (placebo effect) and diagnostics. Within certain drug groups such as analgesics, anti-infectives, cardiovascular and dermatological agents, suggestions to add or delete certain drugs, reflected not always scientific soundness but rather opinions and experiences, as well as prescribing and consumption patterns in different parts of the world. A few persons from

countries with many expatriate physicians educated in different systems felt that the annotated list fell short of the expectations of the practicing physicians whose continuous requests for inclusion of certain drugs on a selected drug list posed problems.

The comments were analyzed and, together with other information gathered from who factfinding missions in developing countries, served as background material for the first Expert Committee on the Selection of Essential Drugs in 1977. This Committee also had at its disposal three main working papers, prepared by three different who expert panel members (pharmacologists/clinicians), who independently had established criteria for selection of drugs having based their choice on available reputable sources on drug efficacy and safety.

## 2.2. *First Expert Committee on the Selection of Essential Drugs*

### 2.2.1. First Model List

The report, Technical Report Series 615 (5), from this Expert Committee became a who bestseller when it was published in 1977. Reactions from the pharmaceutical industry were initially negative. However, what six years ago could perhaps be called an atmosphere of confrontation today, through a continuous dialogue between the industry and who, has changed into a willingness for collaboration.

I must stress that the who list is a "model" or "guiding list", which is meant to serve as a basis for countries to identify their own priorities and to make their own selection. A list of essential drugs can take care of the majority (80-90%) of health problems amenable to any treatment. It does, however, not mean that other drugs are not useful, but simply that in a given situation these essential drugs are the most needed for the health care of the majority of the population and, therefore, should be available in adequate amounts and in the proper dosage forms.

The preparation of a drug list of uniform, general applicability is not feasible or possible because of the great inter-country differences. Each country, therefore, has to evaluate and adopt a list of essential drugs, according to its own health policy.

In the First Expert Committee report, it was emphasized that *criteria for the selection of essential drugs* are intended to ensure that the process of selection will be unbiased and based on the best available scientific information, yet allow for a degree of variation to take into account local needs and requirements. Guidelines recommended that :

- 1) *each country should appoint a committee* to establish a list of essential drugs ; the committee should include individuals competent in the fields of medicine, pharmacology, and pharmacy as well as peripheral health workers

2) drug selection should be based on the results of *benefit and safety evaluations*

3) the *international non-proprietary* (generic) names for drugs or pharmaceutical substances should be used whenever available, and prescribers should be provided with a cross-index of non-proprietary and proprietary names

4) *quality*, including stability and bio-availability, should be assured through testing or regulation

5) *cost* should be an important consideration, not only the unit cost, but the cost of the total treatment in cost comparisons between drugs

6) local health authorities should decide the *level of expertise required to prescribe* single drugs or a group of drugs in a therapeutic category

7) the influence of local diseases or conditions in pharmacokinetic and pharmacodynamic parameters should be considered in making the selections : e.g., malnutrition, liver disease

8) when *several drugs* are available for the *same indication*, the drug, pharmaceutical product and dosage form that provide the highest benefit/risk ratio should be selected

9) when *two or more drugs* are *therapeutically equivalent*, preference as to which one to choose should be based on specified conditions : e.g. the drug that has been most thoroughly investigated

10) *fixed ratio-combination* should only be accepted under certain conditions : e.g., to improve compliance

11) a *national essential drug list* should be reviewed at least once a year and whenever necessary and *new drugs* should be introduced only if they offer distinct advantages over drugs previously selected.

In the application of its guidelines, this First Expert Committee gave some examples of drugs which had been either excluded or included in the model list. A drug like chloramphenicol was included in spite of being capable of causing severe adverse effects, whereas others such as phenylbutazone were excluded. The consensus was that the benefit of chloramphenicol when properly used, outweighed its risks, whereas the same was not true for phenylbutazone since other drugs were available with a better benefit/risk ratio. Cloquinol and noramidopyrine were excluded for similar reasons.

Instead of giving examples of individual drugs, included or excluded in the WHO model list, it is perhaps more important to stress a principle adopted in the First Expert Committee which has been clarified and emphasized in subsequent expert committee reports. This principle (indicated originally by number 1, later by a symbol) refers to the listing of a drug *as an example of a therapeutic group* : e.g., propranolol among the beta blockers, chlorphenamine among the antihistamines, ibuprofen among the non-steroid anti-inflammatory drugs, hydrochlorothiazide among the thiazide diuretics. At the national

level, choice should be influenced by the comparative costs and availability of equivalent products as acceptable substitutions.

### 2.2.2. Drug Information and Education

How drugs are used (i.e., the dosage, duration of treatment, follow-up, and compliance) is often a bigger problem than the choice of drugs. To promote proper use and rational prescribing, information about drugs is needed at all health care levels: i.e., regulatory authorities, doctors, pharmacists, nurses and other paramedical personnel and the consumer. The type of information required can be classified as: pharmaceutical, pharmacological, clinical and economic. The content of information should be suited to the level of education of the health workers. A sample of model drugs information sheets was given in the First Expert Committee report, also stressing the need to adjust it to the requirements and abilities of the prescriber.

The need to educate health care professionals throughout their professional lives (through training seminars, articles in medical journals, and newsletters) and also consumers about drugs is of utmost importance. Education of the consumer is particularly important at the primary health care level where a significant proportion of drugs' usage is self-medication.

### 2.3. *Second Expert Committee on the Selection of Essential Drugs (6): First Revision of Model List*

In 1979 a Second Expert Committee met to review and update the model list of essential drugs contained in the first report, which had been widely circulated with requests for comments. The responses to this request, as well as many unsolicited comments, were collated and presented to a preparatory meeting convened in 1978. Proposals for the revision and updating of the first model list were contained in the report of that meeting (7). Details of commonly-used dosage forms and strengths selected for the drugs in the model list were also included in the preparatory report, which was used as reference document for the Expert Committee members.

No modification of the first model list was introduced unless definite advantages were considered to accrue from the changes. Short comments were provided where changes had been made. Incidentally, this concept of commenting on the reason for including or excluding a drug in the model list had been a highly controversial issue at the First Expert Committee meeting, which at that time decided to leave it out. Some members of the committee felt very strongly that the reasons should be stated in the report. Others were of the opinion that the committee was not writing a textbook in pharmacology! Retrospectively, I believe the committee's decision was wise, curbing endless discussions and polemics with interested parties which would have occurred in

1977 when the first list was published. Instead, the committee based its decision on the guiding principles to justify the selection of the drugs in the model list.

If one classifies the changes made in the second report into *deletions*, *additions*, and *amendments*, 13 drugs were deleted from the approximately 250 main and complementary drugs from the first list; 42 were added; and amendments were made to 66 drugs, mostly in the form of adding explanatory notes.

Pharmaceutical dosage forms and strengths were introduced in the Second expert Committee report, the choice being based on worldwide availability and common usage. The need for accurate and objective information about each drug in a national list of essential drugs was again stressed. It was also suggested that seminars or workshops, organized in developing countries on the selection and use of essential drugs – particularly, in primary health care, could help to identify the type of basic information that should accompany the WHO model list in order to make it more useful and easier to understand. The Second Expert Committee also underlined the importance of exchanging information with the pharmaceutical industry on the drugs included in this model list to ensure the availability of raw materials and of the most appropriate and economical pharmaceutical dosage forms to meet the health needs of developing countries.

#### 2.4. *Third Expert Committee Report "The Use of Essential Drugs" (8) ; Second Revision of Model List*

Since the first report on the selection of essential drugs was published in 1977, the concept of essential drugs had become widely recognized as useful. At the time when the Third Expert Committee met in December 1982, WHO had information that some 70 developing countries had established lists of essential drugs for the public sector or national formularies. In some countries essential drug programmes had emerged and were in an advanced stage of implementation.

In the third report, the guiding principles of the previous reports were reiterated and included. The explanatory notes were made clearer; e.g., a square symbol (□) indicating "example of a therapeutic group" and the numbers in parentheses following the drug names and referring to the explanatory notes were revised. Fewer deletions and additions of drugs were, however, made than in the second model list. In some cases, such as the use of timolol in glaucoma and the addition of cephalosporine, it was considered premature to include drugs of considerable promise on the list. Important modifications were, however, made – particularly in relation to anti-infective drugs and to certain dosage forms and drug strengths.

Peculiarities and also difficulties when selecting and revising drug lists even when done with a two-year interval by experts, are illustrated by two examples. Spironolactone was introduced in the first list, deleted from the diuretics in the second list (reasons given that it can be replaced by amiloride), and reintroduced in the third list. Thioacetazone was a complementary drug in the first list. The Second Expert Committee deleted the drug from the list of complementary anti-tuberculosis drugs noting "its doubtful efficacy". From the experts on tuberculosis treatment in developing countries, it was strongly recommended, however, to reintroduce thioacetazone, in combination with isoniazid, since it is effective and cheap therapy and widely used.

The emphasis on *the usage of drugs* (the Expert Committee report is called "The Use of Essential Drugs") is also evident from the discussion of drug information sheets for doctors, prepared in draft form in response to a recommendation in the first report of the Expert Committee on the Selection of Essential Drugs.

These draft drug information sheets are now subject to broad consultation and will eventually be issued together with general advice on therapeutic matters in a who model formulary with pharmacological, clinical and pharmaceutical information.

One important addition to this last report, published in 1983, is the inclusion of a *model list for primary health care of twenty-two substances* from the main list. The first report of the Expert Committee on the Selection of Essential Drugs had recommended a compilation of such a list, and this has now been done. Again, it is at the national level that the drugs suitable for a country's primary health care system need to be selected, depending on the level of education and training of the health care workers.

The twenty-two selected primary health care drugs in this Committee Report can, however, be used efficiently and safely by responsible individuals with little formal medical knowledge.

### 3. TRANSITION FROM CONCEPT TO PROPOSALS FOR PROGRAMMES ON ESSENTIAL DRUGS

From 1976 who staff gathered facts and first-hand information in developing countries in order to have a clear idea of the problems to be tackled in the pharmaceutical sector. who Regional Offices organized visits to 25 countries (9) during 1976 and 1977, while surveys of the pharmaceutical supply system were undertaken by nationals in their own countries in collaboration with who staff. who, thus, learned about the real situation from government officials, health workers in rural areas, doctors and pharmacists at different levels of health services, and managers of pharmaceutical factories. The facts and data gathered during the visits were analyzed and discussed in order to identify the main problems, which prevents large segments of the

population in developing countries from having access to the most needed drugs.

In 1978 regional programmes for technical cooperation in drug policies and management were being developed. Meetings of experts from the countries of the who Western Pacific and South East Asia regions were convened in Manila and Colombo to review the *regional* situations, identify problems, and establish suitable strategies for an action programme with and among countries in the region.

In 1978 the who Executive Board proposed in Resolution EB61.R17 (10) an action programme of technical cooperation on essential drugs, including the importance of dialogue and collaboration with the pharmaceutical industry. The same year, technical discussions were held during the World Health Assembly on the subject of "National Policies and Practices in regard to Medicinal Products and related Problems" (11). Several hundred participants attended and took part in the discussions on policies and practices in regard to medicinal products and the technical and administrative components of drug policies and management. Following a presentation of the above-mentioned progress report on drug policies and management, the 1978 World Health Assembly passed Resolution WHA31.32, entitled Action Programme on Essential Drugs (12). Member States were urged to establish drug lists and adequate pharmaceutical supply systems, enact legislations, and collaborate with who and aid agencies in doing so. who's Director-General was, in turn, requested to study ways of giving necessary support to the Member States and to develop further dialogue with pharmaceutical industries to ensure their collaboration in meeting the health needs of under-served segments of the world's population.

At the Thirty-second World Health Assembly in 1979, Resolution WHA32.41 called for the establishment of a special programme on essential drugs, including its administrative structure and to make provision for the initial financing, if necessary (13).

In February 1981 the who Action Programme on Essential Drugs was officially established. This programme operates in a complex technical, social, political and economic environment and deals with delicate issues, which perhaps can explain its initial growing pains and search for identification and direction.

#### 4. IMPLEMENTATION OF THE ESSENTIAL DRUG CONCEPT AT GLOBAL, REGIONAL AND NATIONAL LEVELS (14)

##### 4.1. *who Action Programme on Essential Drugs*

The who Action Programme on Essential Drugs is a worldwide collaborative programme of Member States, WHO, UNICEF, other organiza-

tions of the United Nations system, the pharmaceutical industry and other institutions - both public and private (15). The objective of the programme is to support Member States to develop and improve their drug supply systems, ensuring the availability of safe and effective drugs and vaccines of acceptable quality and at the lowest possible cost in support of primary health care.

Pharmaceutical supply systems have evolved to some degree in all countries. In the Least Developed Countries (LDC) usually only some components of the systems are present, in contrast to the industrialized countries where all components are present, although not always coordinated. Because of conflicting goals and needs that must be met and because of the changing inter-play of economic, scientific, political, etc. pressures, the pharmaceutical supply system undergoes continuous changes in all countries.

What exactly are, then, the problems in a developing country? The following ones concerning acquisition, distribution and usage of drugs will serve as examples. They were identified during a WHO workshop in 1982 in Rwanda (16) attended by high-level officials from the Ministries of Health, Finance and Trade.

*List of Problems Identified by Nationals*

- *Meagre resources* to treat a large population ;
- *Tradition* to use medicines instead of emphasizing hygiene and nutrition ;
- *Mediocre health care* inspite of a relatively large number of medically trained personnel ;
- *Indiscriminate prescribing* often resulting in more harm than good ;
- *Inequality in distribution* between urban and rural areas, at the disadvantage of the latter ;
- *Insufficient control* at the port of entry of medicines ;
- *Lack of quality control* of medicines ;
- *Proliferation* of a wide variety of pharmaceutical *products* under different names in the private sector and a lack of objective drug information ;
- *Poor compliance* with existing regulations regarding sale and distribution of prescription medicines ;
- *Periodic shortage* of stocks in the central medical stores ;
- *Very limited possibilities* for the rural population to buy medicines in the private pharmacies when the public sector stock is insufficient ;
- *Deterioration and loss* of medicines due to poor storage and handling conditions ;
- *Non-adherence* by private pharmacies to a national list of essential drugs when they order drugs directly from abroad ;

- Drugs for the different levels of health services are *not allocated and distributed according to needs and levels of prescribers* :

- The *need* for developing and implementing a national drug policy.

Before giving examples of approaches and activities to solving the problems at country level, I will describe the principles and main lines of action of the WHO Programme on Essential Drugs.

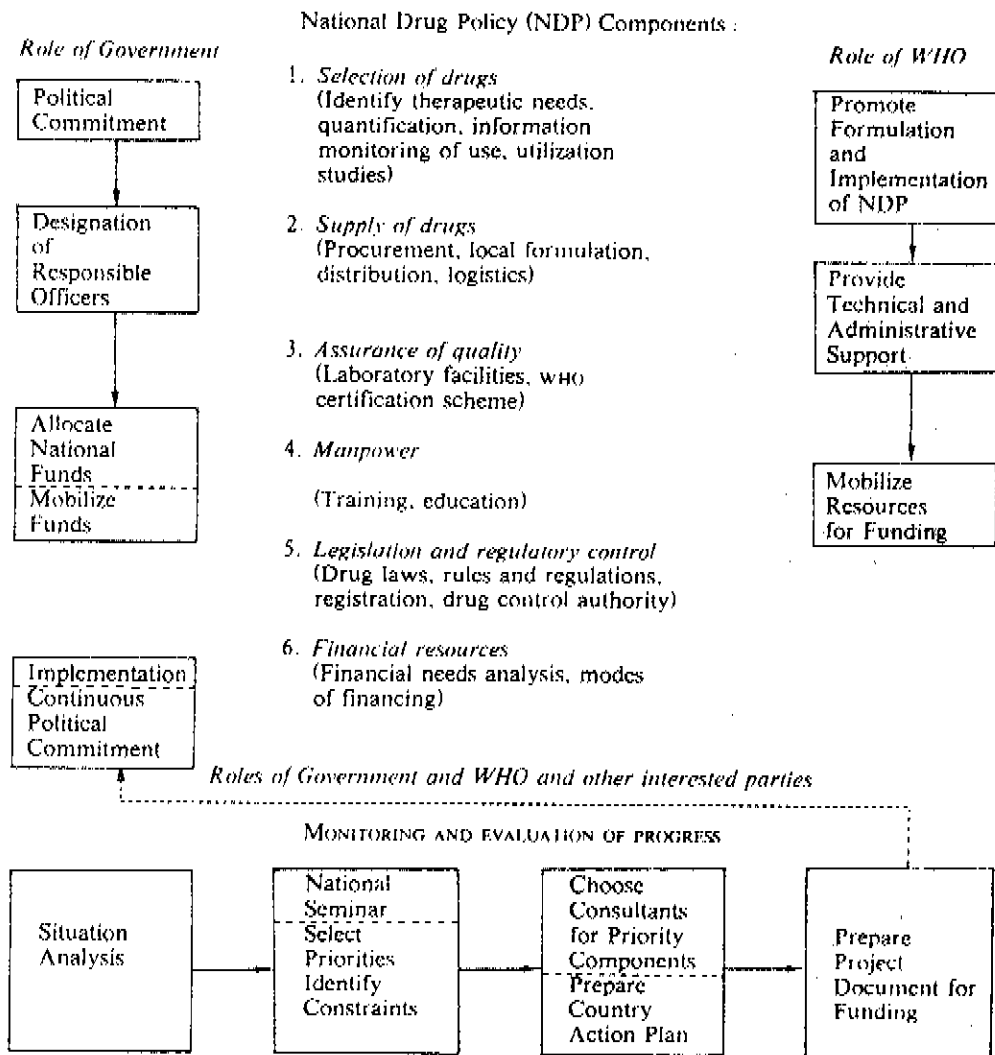
The World Health Organization provides worldwide leadership and coordination for the Programme to arouse enthusiasm and commitment to participate in it. WHO cooperates with Member States on request and ensures the availability of necessary expertise. The Organization works closely with national governments, other organizations of the UN system and in particular UNICEF, non-governmental organizations, bilateral donor agencies (e.g., DANIDA and SIDA), and other institutions including the pharmaceutical industry. The Action Programme is financed by WHO's regular budget and from other sources, such as bilateral, multilateral, and financial institutions.

The development of *national drug policies* is a major objective of the WHO programme. These policies should relate to health systems based on primary health care, should be consistent with the concept of essential drugs, and whenever possible should emphasize preventive health care.

The main activities that have to be considered when formulating a national drug policy are :

- identification of therapeutic needs
- select essential drugs
- estimate quantities needed
- ensure the proper use of essential drugs
- provide information and education
- improve the drug supply system
- local formulation of certain essential drugs (when this is technically and economically feasible)
- local production (only when this proves to be technically and economically feasible and desirable)
- assurance of quality
- introducing appropriate legislation
- monitoring adverse reactions
- ensuring manpower requirements
- ensuring coordinated multisectoral action
- evaluation process
- financial needs analysis and modes of financing.

In Figure 1 the components of national drug policies are grouped together under six major headings which are : *selection, supply, assurance of quality,*



**Fig. 1**  
Example of Development and Establishment of National Drug Policies  
and a Country Action Programme on Essential Drugs.

*manpower, legislation, and financial resources.* Since the Action Programme is a partnership between many partners, but particularly between WHO and Member States, the individual and combined roles of WHO and the Member States Government are schematically shown in Figure 1. The main role of the government is to ensure political commitment for its essential drug programme, to designate responsible officers to carry it out and to allocate at least some additional funds as proof of commitment. WHO at its end provides technical and administrative support and mobilizes resources for funding. Together, often also with other interested partners such as UNICEF and bilateral aid organizations, a situation analysis is carried out; problems are identified; priorities are chosen; and constraints are spelled out. Consultants are chosen for priority components; a country action plan and a project document for funding are prepared leading up to implementation of a country action programme on essential drugs (APED). It cannot be sufficiently emphasized that continuous political commitment and support at country level are absolute necessities for success. This often means tackling those who resist change and who wish to maintain a comfortable and perhaps vested interest in the status quo.

How is, then, progress monitored or evaluated? How do we measure change and how do we know where and on what to concentrate? The WHO Action Programme is now in the process of testing five main indicators which have been chosen to help in assessing progress from one year to another, identify constraints, and concentrate on priority items. If one rephrases the indicators into questions, they are as follows:

1. Is government commitment evident?
  - Formal meeting held?
  - Focal point established?
2. Has a national list of essential drugs been formulated? implemented?
3. Has a country plan of action been drafted? launched?
4. Are financial resources assured?
  - By government/institutions?
  - By ad hoc donors?
5. What percentage of the population have access to at least 20 essential drugs within one hour's walk or travel? (i.e., measure of coverage of drugs).

In answer to the first question, the answer could be: "Yes, a formal meeting was held, the concept of essential drugs was promoted, and in principle it was accepted by participating nationals in key positions. But a major issue to be resolved is how should the momentum be maintained when the Ministry of Health staff is insufficient and overloaded with work and a focal point (a manager or administrator) has not been appointed to coordinate the activities".

The answer to the question if financial resources have been mobilized or assured could be "several piecemeal approaches to donors were made, but without success since donors are not convinced that the government is fully committed to providing primary health care".

#### 4.2. *Examples of Global, Regional, and Inter-regional Activities*

who has a catalytic, coordinating and technical cooperation role to support the concept of essential drugs and its implementation. This includes such activities as bringing together in meetings, seminars, workshops and working groups persons from developed and developing countries, non-governmental organizations, other UN agencies, bilateral agencies, pharmaceutical industries, experts in the different fields involved, and academic and research institutions. An example of such an activity is a recent *regional meeting* in the who South-East Asia Region of about ten countries on identifying areas of regional collaboration in testing drug quality, exchange of drug information, and training of manpower. Another example from the who African Region is a meeting of the Chief Pharmacists held in 1982 in Zimbabwe where ways and means were defined by which the Chief Pharmacists may implement at national level the *regional action programme* on essential drugs with emphasis on : procurement, distribution, production, storage and quality control of drugs and vaccines.

An inter-regional activity on technical cooperation in six areas of pharmaceuticals is going on among the ASEAN countries with financial support from the United Nations Development Programme (UNDP) and who. Caricom and Andean Pact countries are also developing sub-regional policies and positions.

At the global level *guidelines, handbooks and manuals* are being developed covering : (a) selection of drugs and objective drug information accompanying the essential drugs in the model list, (b) national drug policies, (c) drug legislation, (d) training and retraining of manpower, and (e) guidelines related to pharmaceutical technology and quality assurance. But the production of guidelines or manuals do not by themselves guarantee success. Unless they are suited to practical needs and used, they are superfluous. Testing and use at country level through workshops, working groups, and training programmes will, therefore, become an important function of the who Action Programme on Essential Drugs. One such activity will take place in Kenya later this year when that country's new system for supply of essential drugs to rural health facilities will be demonstrated to nine French-speaking and nine English-speaking African countries in two consecutive workshops. These will be followed by a working group which will choose a few concrete problems related to estimating needs, buying, distributing, prescribing, and

dispensing drugs, giving remedies for how the problems can be attacked locally.

WHO is also collaborating with the pharmaceutical industry through the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), which is a nongovernmental organization in official relations with WHO. The industry through IFPMA has offered its support to the Action Programme. More than fifty companies have offered to supply drugs from the WHO model list at "favourable prices". Several pharmaceutical manufacturers are already giving technical support in the form of fellowships (close to 50 so far) in training in quality control. What actually is meant by "favourable" prices is not yet clear, since no prices have yet been quoted. But according to the IFPMA Executive Vice-President (17), "it is impossible for companies to quote prices until the demand has been defined in terms of quantities, pack sizes, dates of deliveries, and so on. Nevertheless, we can be sure that when prices are finally quoted, they will attract a good deal of attention". Negotiations are presently undertaken between IFPMA and WHO to establish practical guidelines for the industry's offer of support for APEDs.

#### 4.3. *Examples of country programmes*

Developing countries vary in size, population, development of infrastructure, trained manpower, etc., and in their needs for drugs and assistance. But the one main objective common to all who embark on a country action programme on essential drugs should be to extend coverage (availability and accessibility) of locally selected drugs for primary health care and to train health workers in how to use the selected drugs.

The following examples are chosen to demonstrate different approaches and stages of implementation in a few selected countries.

*Kenya*: What started as a pilot programme in 1979 has now expanded to cover a large part of the country. Essential drugs, 30 items to dispensaries and 40 to health centers are supplied on a monthly basis to rural health facilities in so-called "ration kits": that is, drugs prepackaged in sealed boxes to cover the needs for a certain time period. The needs have been calculated based on recorded episodes of illness in dispensaries and health centers. Shortage of drugs is no longer an ever recurring problem. Contributing ingredients to the successful Kenya programme are: a drug management and supply unit in the Ministry of Health, which is responsible for procurement and distribution of the drugs, preparation of standard treatment schedules, manuals for clinical diagnosis, training of health workers, and information to the public.

The Kenya programme was initially assisted by WHO and is now supported by the Danish (DANIDA) and Swedish (SIDA) aid agencies.

*Tanzania*: In Tanzania an essential drug programme built upon the same principles as the one in Kenya is about to start with the help of UNICEF.

WHO, the World Bank, and DANIDA – who is contributing US\$ 30 million over a three-year period.

*The Gambia* : In this small African country with a population of about 0.6 million, several U.S. pharmaceutical companies have assisted the government with drugs and improvements in the supply system. The whole distribution system has been reorganized, and the list of drugs has been cut from over 200 to around 130 items. The Ministry of Health has also trained so-called village health workers (VHW) to dispense 14 basic drugs, including penicillin tablets. These village health workers, many of them illiterate, receive six weeks of training. But they are regularly visited by a nurse-supervisor from the health centers. A new drug legislation, drafted by who at the request of the Ministry of Health, is now being submitted to Parliament for review and enactment, primarily to serve as the basis for a national drug policy.

*Bangladesh* : On 12 June 1982, the Ministry of Law and Land Reforms in Bangladesh (population 85 million in 1981) published a New Drug Control Ordinance introducing a new national drug policy with a list of 1 700 drugs to be removed from the market. Several combination drugs, vitamin products, tonics, and drugs of dubious therapeutic value will not be allowed to be imported or sold in the country. The Bangladesh Ordinance only allows for essential drugs to remain on the market. Only 10% of the currently available drugs in Bangladesh are supplied through the public sector (18), and the regulations will affect mainly the private sector. who, together with SIDA and DANIDA, are now collaborating with Bangladesh to support and upgrade quality control and local production facilities and is also attempting to estimate and quantify the therapeutic needs, to extend coverage of drugs in the public sector with emphasis on primary health care.

*Indonesia* : In Indonesia (population 150 million, 1981), a new drug policy has been adopted. Efforts have been concentrated on upgrading the drug regulatory control mechanism, i.e., evaluation and registration of drugs, drug information, adverse reactions, drug utilization studies, etc. Drug quality control and good manufacturing practices are other matters attended to in Indonesia, which has over 260 producers of pharmaceutical products. United Nations Development Programme (UNDP) and who give financial and technical support to the Indonesian activities.

*Barbados* : A drug service for the public sector has been established. It provides centralized procurement, coordinates distribution, monitors use and gives objective drug information to health care personnel. The Barbados Drug Service was recently designated as a who Collaborating Center for Drug Management.

*Rwanda* : Upon request of the government, a factfinding mission assisted Rwanda in 1980. Experts from the Danish Ministry of Health and the Danish pharmaceutical industry took part in the mission, together with who staff. The

mission identified problems and constraints in the Rwanda drug supply system and recommended to hold a national workshop, with the purpose of promoting the concept of essential drugs and formulating a national drug policy. A workshop entitled "Health and Drugs" was organized by WHO and the Ministry of Health and was held in November 1982. DANIDA gave the financial support.

From the long list of recommendations that followed, the first steps to be taken are to select the drugs appropriate for use at the hospital, health center, and dispensary levels. Standard treatment schedules in a therapeutic guide are also under preparation, as well as a country plan of action to be used for securing funds to implement an essential drug programme in Rwanda. A pilot project in support of primary health care and including an element of drugs will start in one district in 1984. This project is being funded by the Belgian government.

*Ethiopia and Guinea-Bissau*: UNICEF/WHO and the Italian government, which has made a commitment to donate US\$ 15 million toward the Action Programme on Essential Drugs, are expected to start implementation of joint programmes by the end of 1983 in these two countries and later on in three other African countries.

## 5. CONCLUSIONS

Since its first publication in 1977, the WHO concept of essential drugs has become widely known and accepted as a very useful tool towards rational drug usage. Developing countries whose resources and trained manpower are scarce cannot afford to spend their money on non-essential drugs and should, therefore, through their own National Formulary Committees select those drugs that are suitable for their therapeutic needs. In doing so, the WHO model list of essential drugs continues to serve as guidance and reference. The principles and criteria formulated in the first Expert Committee Report on the Selection of Essential Drugs, reiterated and emphasized in the Second and Third Report, lay the foundation for the individual drug selection. The selection of essential drugs for different levels of health care (i.e., hospitals, health centers, dispensaries) in a developing country is only the starting point in a long row of activities which include quantifying the amounts needed, improving the drug distribution system, teaching health workers how to use the drugs, preparing therapeutic guides, introducing appropriate legislation, etc., and monitoring and evaluating the progress. The WHO Action Programme on essential Drugs gives technical and administrative support to developing countries and mobilizes funds for implementing national drug action programmes. It operates in a highly complex environment with a delicate subject matter but has as its main goal to ensure the availability and

accessibility of essential drugs for primary health care. These efforts can only succeed in a country where there is political commitment and support for the cause.

#### REFERENCES

1. IMS Pharmaceutical Marketletter September 19. 1983. IMSWorld Publications Ltd.
2. Off. Rec. Wld. Hlth. Org., 1975, No. 226, pp. 35-36.
3. Off. Rec. Wld. Hlth. Org., 1975, No. 226, Annex 13, pp. 96-110.
4. Unpublished who Document DPM/76.1.
5. who Technical report Series No. 615, "The Selection of Essential Drugs", 1977.
6. who Technical Report Series No. 641, "The Selection of Essential Drugs", 1979.
7. Unpublished who Document DPM/79.2.
8. who Technical Report Series No. 685, "The Use of Essential Drugs", 1983.
9. Drug Policies and Management : Progress Report by the Director-General, Thirty-first World Health Assembly Document A31/12, 11 April 1978.
10. Off. Rec. Wld. Hlth. Org., 1978, No. 244, pp. 11-12.
11. Background document for reference and use at the Technical Discussions, Document A31/Technical Discussions/1, 6 March 1978.
12. Off. Rec. Wld. Hlth. Org., 1978, No. 247, pp. 20-21.
13. World Health Organization. Resolutions and Decisions Annexes, WHA32/1979/REC/1.
14. World Health Organization : Action Programme on Essential Drugs, report by the Executive Board Ad Hoc Committee on Drug Policies on behalf of the Executive Board, Document A35/7, 1 April 1982.
15. World Health Organization : Action Programme on Essential Drugs World Health Assembly (WHA) Resolution 35.27, 14 May 1982.
16. World Health Organization : Report of the Workshop on "Health and Drugs", Rwanda, 7-12 November 1982, DAP/83.2.
17. PEREIZ, S. M. : IFPMA's current activities and involvement with UN agencies. *In : Pharmaceuticals in Developing Countries, papers presented at the Eleventh IFPMA Assembly, Washington, D.C., 7-8 June 1982.* pp. 71-78.
18. PEREIZ, S. M. : Pharmaceuticals in the Third World, Tropical Doctor, January 1983.

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