



Technical Discussions



BACKGROUND DOCUMENT

for reference and use at the

TECHNICAL DISCUSSIONS

ON

"NATIONAL POLICIES AND PRACTICES IN REGARD TO MEDICINAL PRODUCTS;  
 AND RELATED INTERNATIONAL PROBLEMS"

This document outlines:

(a) various aspects of the current policies and practices in regard to medicinal products and trends in formulating national drug policies taking into consideration the health priorities;

(b) technical and administrative components in policies and management for establishing a pharmaceutical supply system to meet the health needs.

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## 1. INTRODUCTION

1.1 This background document for reference and use at the Technical Discussions to be held during the Thirty-first World Health Assembly has been prepared by the Secretariat on the basis of previous discussions at different levels of the Organization, visits of staff members to a number of countries, country surveys undertaken by nationals in collaboration with WHO, various consultations and publications. Recognizing the complexities of the subject, it focuses, in accordance with recent resolutions of the governing bodies of WHO, on the health needs of populations, particularly in developing countries, and on medicinal products that are indispensable for effective health care. Herbal remedies and traditional medicines are considered within the framework of a better utilization of locally available resources.

1.2 It is expected that the Technical Discussions will provide an opportunity to review drug policies as they relate to health priorities, and to exchange views and experiences at national, regional and global levels, especially on technical cooperation among countries and on the role of WHO.

1.3 In 1975, the Twenty-eighth World Health Assembly considered a comprehensive report of the Director-General<sup>1</sup> which reviewed the main components of drug policies, involving not only the health sector but also the industry, trade and financial sectors, outlined problems in developed and developing countries and emphasized the need for adequate policies in order to meet the needs of developing countries where large segments of the population do not have access to the most essential drugs and vaccines indispensable to ensure effective health care. In resolution WHA28.66, the Assembly stressed the need of developing drug policies linking drug research, production and distribution with the real health needs and requested inter alia the Director-General to advise countries on the selection and procurement, at reasonable cost, of essential drugs of established quality corresponding to their national health needs.

1.4 The Executive Board at its Sixty-first Session in January 1978, having reviewed the Report of the Expert Committee on the Selection of Essential Drugs<sup>2</sup> and a progress report on Drug Policies and Management<sup>3</sup> by the Director-General, adopted resolution EB61.R17, calling for urgent international action aiming at strengthening the national capabilities of the developing countries in the field of selection and proper use of essential drugs to meet their real health needs, and in local production and quality control, wherever feasible, of such drugs. The Board requested the Director-General inter alia to maintain a dialogue with the pharmaceutical industry in order to assure its collaboration in meeting the health needs of large underserved segments of the world's population, and to appeal to governments and the pharmaceutical industry to participate in WHO's action programme on essential drugs. The following information on regional activities was also provided to the Executive Board:

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<sup>1</sup> WHO Official Records No. 226, 1975, Annex 13, pp. 96-110

<sup>2</sup> WHO Technical Report Series No. 615, 1977

<sup>3</sup> Document EB61/WP/2

1.4.1 The Regional Committee for Africa adopted, at its Twenty-seventh Session in 1977, a resolution requesting the Regional Director to: (1) follow closely the progress of a feasibility study on the establishment of a pharmaceutical industry in the Region with the collaboration of the African Development Bank; (2) set up a multidisciplinary working group to examine, in the short and medium term, mechanisms for obtaining pharmaceutical and biological substances and medical supplies and, in the short term, all the implications of establishing a pharmaceutical industry in the Region; (3) pay special attention to the training of all categories of personnel, particularly those concerned with the management, production, preservation, quality control, transport and distribution of pharmaceutical and biological substances and medical supplies; (4) ask the Director-General to make all necessary approaches to the representatives of major drug producers and distributors, with a view to obtaining a reduction of prices.

1.4.2 The Regional Committee for the Americas in 1977 adopted two resolutions at its Twenty-ninth Session, one determining that the subject for the Technical Discussions in 1978 was to be, "The impact of drugs on health costs", and the other authorizing the Director of PAHO to establish a working fund so that the Organization would be in a position to supply vaccines and other biological substances for immunization purposes. From preliminary studies, a sum of US\$ 5 000 000 has been estimated as being required for this purpose.

1.4.3 In 1977 the Regional Committee for Europe considered items related to drug policies during discussions on the Regional Director's Development Programme. The first regional research priority group on the evaluation of drugs met in February 1978 and, as funds are approved, additional staff will be appointed for work on drug policies, including training of pharmaceutical personnel.

1.4.4 In 1977, drug policies and management were included in the annual report of the Regional Director to the Regional Committee for the Eastern Mediterranean. The rapid development of health and hospital services in the Region had increased the need for pharmaceuticals. Unfortunately, practitioners were prescribing increasingly expensive drugs so that in some countries 30 per cent or more of the health budget was spent on drug supplies (one country had reported an expenditure of 53 per cent). Studies are in progress to determine drug requirements and drug utilization in primary health care and hospitals, in order to obtain basic data for national drug policies. There was unanimous agreement that a reduction of the unlimited variety of pharmaceutical preparations in national and international markets to an easy-to-survey selection of essential drugs was a basic requirement for rational drug supply and use.

1.4.5 The Regional Office for South-East Asia has initiated a project of technical cooperation among the countries of the Region in the field of drug policies and management, starting with studies of the pharmaceutical sector by nationals in their own countries, in collaboration with WHO. A meeting was convened in Colombo in March 1978 to discuss the results of the studies with a view to developing technical cooperation among the countries to reach an understanding of the problems involved and possible solutions. The quality control aspects were discussed at a workshop in New Delhi in January 1978.

1.4.6 At the Regional Committee of the Western Pacific in 1977, the subject of the Technical Presentation was "National Drug Policies and Management" and this was followed by country studies. A Working Group was convened in Manila in March 1978 to review the results of the country surveys and to plan regional activities in the field of drug policies and management to be implemented in 1979.

1.5 Within their terms of reference, other United Nations agencies and organizations have developed activities related to medicinal products, particularly UNICEF. A joint UNCTAD, UNDP, UNIDO and WHO programme has been initiated entitled, "Economic and Technical Cooperation among Developing Countries in the Pharmaceutical Sector" (Executing Agency: Ministry of Foreign Affairs of the Government of Guyana).

1.6 Problems related to medicinal products were discussed in 1976 at the Fifth Conference of Heads of State or Governments of Non-Aligned Countries in Colombo and at the Conference on Economic Cooperation among Developing Countries in Mexico City.

## 2. POLICY TRENDS IN REGARD TO MEDICINAL PRODUCTS

2.1 The definitions of "drugs", "medicines", "pharmaceutical products" and "medicinal products" vary from country to country. These terms usually mean the substances and/or the products used in man for prophylactic, diagnostic and therapeutic purposes, including substances of synthetic or natural origin, biologicals such as vaccines and sera, and, in some cases, blood and its derivatives.

To meet the health needs and demands of the population, medicinal products are supplied through a country-wide system of established institutions involved in various activities such as procurement, production, control of drugs and vaccines, drug research and development, distribution to health services and to the public, monitoring of marketed products, etc. (see section 5). The term pharmaceutical supply system is used to describe all activities which form a more or less coherent system partly related to the health care system and partly to the industry, trade and financial sectors.

2.2 Pharmaceutical supply systems have evolved to some degree in all countries, ranging from the less developed countries, where only some components are present, to the industrialized countries, where all components are present, although not always coordinated to form a coherent system. Because of conflicting goals and needs that must be met, and because of the changing interplay of political, economic and social pressures, the pharmaceutical supply system undergoes continuous changes in all countries. These pressures are often conflicting because of the diverse interests of the groups involved: government, commercial enterprises, medical profession, scientific and academic community, etc.

2.3 Depending on a country's constitutional, organizational and administrative structures, form of government and level of socio-economic development, its pharmaceutical supply system may be part of the state system, or of another public sector organization, or may belong to the private sector or be partly

in the public sector and partly in the private sector. All the components of the pharmaceutical supply system may be under the authority of the health ministry, or some components may be under its authority whilst others may be under the authority of different sectors of the government, such as industry, trade and finance. Problems of cooperation and coordination vary accordingly, not only between the pharmaceutical supply system and the health care system, but also among the different components of the pharmaceutical supply system itself. In countries where the pharmaceutical supply system is in the private sector, more or less stringent regulatory control mechanisms exist because medicinal products have an important impact on the health of the people and on the national economy. In other words, balanced drug policies require an integration of health and social policies with industrial and technological components.

2.4 The aim of developing clearly formulated national drug policies is to achieve better efficiency of the pharmaceutical supply system through better cooperation and coordination of its different components and of the different sectors involved, mainly health, trade, industrial production, finance, etc. As the main objective of national drug policies should be the accessibility of the most effective and safe medicinal products of established quality, at reasonable cost, to all people, there is a need to plan and review the pharmaceutical supply system as a whole in the light of this objective.

2.5 While medicinal products alone are not sufficient to provide adequate health care, they do play an important role in protecting, maintaining and restoring the health of the people. In spite of the general recognition that medicinal products should be viewed as essential tools for health care and for the improvement of the quality of life, it is not uncommon to find that drug policies are mainly directed towards industrial and trade development and sometimes contradictory policies exist independently and are implemented in different sectors of the administration.

2.6 In developing countries where programmes are implemented to extend the health care coverage to all people, pharmaceutical supply has become a crucial issue. National drug policies often focus on the health needs of essential drugs and vaccines indispensable for the health care of large segments of the population rather than on the demands of the privileged minority who have access to sophisticated medical care in urban areas. In these countries there is a tendency to develop national drug policies aiming at self-reliance through:

- procurement from multiple sources by central or regional agencies (section 5.5);
- establishment of government-owned production facilities and, where appropriate, encouragement of private drug manufacturing (section 5.6);
- limiting the range of available medicinal products and selection of essential drugs to meet the health needs of the majority of the population (section 5.3);

- building up a national quality control system linked with procurement and local production (section 5.4);
- improved utilization of locally available natural resources, particularly medicinal plants, in health care and in local pharmaceutical production (section 5.11);
- establishment of national or regional drug distribution networks parallel to the health services networks (section 5.7);

2.7 In countries which have reached a certain stage of development, an important aspect of national drug policies is the building up of a strong domestic pharmaceutical industry as an important national asset because it constitutes a vital component of the health care system, it is a source of tax revenues and of foreign exchange and savings, it has a strategic value in the supply of vitally needed pharmaceuticals and is a stimulus in research in the medical, biological, chemical and industrial fields. Multisectoral approaches to policy formulation, and mechanisms for coordination and cooperation, are required because, while one aspect of national drug policies concerns delivery of optimal health care in terms of the quality, cost and distribution of medicinal products, another aspect concerns national economy, export and technological development.

2.8 Another aspect of drug policies is closely linked to social security and health insurance schemes which provide medicinal products free of charge to the whole population, or to particular segments of the population. In many countries, it is felt that the availability of free medicinal products, combined with commercial pressures, may lead to over consumption or to wastage through poor patient compliance to prescription. As pharmaceutical expenditure is increasing, means are being sought to achieve better utilization of resources through cost-sharing schemes, restricted lists of reimbursable medicinal products and price controls.

2.9 One important drug policy issue concerns the evaluation of the risk versus benefit ratio of new drugs to be introduced on the market. Regulatory demands for the introduction of new medicinal products are becoming stricter in many countries and the question has been raised as to whether they are becoming too stringent, leading to excessive delays and curtailment of drug research and development. This applies particularly to requirements for animal toxicology testing where measurement methods in this field have progressed beyond the ability to interpret the health implications. Sophisticated controlled clinical trials to measure efficacy have also been criticized because they do not always adequately reflect the use of drugs in medical practice.

2.10 There are important differences in the types of medicinal products required for health care in developed and developing countries. For example, in developed countries, where there is a sufficient supply of medicinal products to meet the basic health needs of the whole population, the demand is increasing for certain types of medicinal products used in chronic diseases of the adult or aged population or for psychic conditions, often linked with living conditions in industrialized societies. The same

demands can be found in many urban areas of developing countries, but the implementation of primary health care programmes in larger segments of the population, and the control of the major communicable diseases, requires a range of medicinal products which is not currently used in the developed countries, particularly those used against malaria and other parasitic diseases prevailing in tropical areas.

2.11 Although the formulation of national drug policies is clearly a matter of national sovereignty to be decided by the authorities in each country, in consultation with the relevant professional organizations, such policies are, to an increasing extent, influenced also by international policies, particularly those of the transnational pharmaceutical corporations. This is due to the fact that international trade in raw materials and finished pharmaceutical products is continually increasing and very few countries can be entirely self-sufficient in pharmaceutical supply. Furthermore, national policies are often influenced by information in medical journals and in the press which stimulates the demands of physicians and consumers for certain medicinal products which are promoted on international markets by transnational corporations.

2.12 The formulation of national drug policies is particularly important for developing countries in order for them to make progress in the pharmaceutical sector and to develop technical and economic cooperation in this field among themselves or with industrialized countries. When policies include provisions for foreign capital investment and transfer of technology, they often clearly indicate the government's medium- and long-term objectives in the sector in order to prevent operations which may jeopardize the development of national capabilities and self-reliance.

2.13 The question has been raised as to whether medicinal products, particularly those indispensable for meeting the basic health needs of the population, should be considered as ordinary commodities subject to the normal forces of market offer and demand. It is true that most pharmaceutical manufacturers are commercial enterprises whose aim is to increase their share of national and international markets. The main criticisms of certain pharmaceutical companies are related to the pricing of medicinal products, the quality of promotion and information on the products, drug research and development policies oriented towards lucrative markets instead of real health needs, product exclusivity through patents and brand names, market collusion and, in developing countries, strategies with regard to ownership of local production facilities, raw materials' pricing and limited transfer of technology. The conflicts between concepts of social justice and public interest, and the commercial interests of the pharmaceutical industry have led many industrialized countries to apply stringent regulations to limit the freedom of pharmaceutical enterprises. However, similar regulations are difficult to implement in most developing countries and there are no international regulations applicable to medicinal products entering into international commerce, although Article 21 of the WHO Constitution gives authority to the World Health Assembly to adopt such regulations.

2.14 Owing to the complexity of the pharmaceutical supply system, and its implications on national interests, there is as yet insufficient agreement among countries to formulate comprehensive international policies on medicinal products, although some progress has been made in groups of countries, such as in the European Economic Community, in harmonization of national drug policies and drug legislation.

2.15 The fundamental prerequisite for the development of balanced drug policies is recognition, by public officials and industry leaders, of mutual dependence and of the necessity for dialogue and negotiation. The industry will be operating in an even more controlled environment because of growing consumer demands for better health care and of public policies to enhance concepts of social justice through careful allocation of national economic resources. To achieve public policy goals, regulation of certain components of the pharmaceutical supply system should be based on understanding, knowledge and foresight of its implications on other components in order to avoid unexpected adverse consequences or counter-productive results.

### 3. TRENDS IN PRODUCTION AND TRADE OF MEDICINAL PRODUCTS

3.1 Production of medicinal products can be divided into three distinct stages:

- production of raw materials and intermediates;
- production of finished dosage forms from half-finished intermediates and raw materials (formulation);
- packaging of finished products or repackaging of bulk finished products.

3.2 For medicinal products derived from vegetable or animal sources, the production of raw materials is partly independent of industrial development and most of these materials can be found both in developed and in developing countries. From these natural sources some important pharmaceuticals are produced which are exported by developing countries as raw or semi-processed materials, to countries with more advanced industries, or they are used to cover their own health needs, for example, medicinal plants.

3.3 For synthetic pharmaceuticals, which represent the largest part of pharmaceutical production and trade on a world scale, the production of raw materials and intermediates normally requires high technology and large-scale production capabilities in order to compete on international markets. It is carried out mainly in industrialized countries having a well developed fine-chemical industry and the large transnational corporations tend to centralize this type of production for economic reasons. However, there are pharmaceutical chemicals which can be synthesized economically in relatively small plants in developing countries having reached a sufficient level of socio-economic development to have built up their own chemical industry.



3.4 The production of finished dosage forms (formulation) from half-finished or intermediate materials includes tableting and the production of injectable liquids and ointments, etc. It can be carried out in small units and requires adequate "know-how", equipment and quality control facilities. This type of pharmaceutical production is carried out in many developing countries, mainly from imported synthetic materials and from locally available raw materials of natural origin.

3.5 Packaging of finished products is the final stage of pharmaceutical production, but it is not without its pitfalls if inadequately controlled. This type of operation can be carried out in the less developed countries having units for repackaging of finished products imported in bulk.

3.6 The final output of the pharmaceutical industry is the finished products which are the main indicator of market size, consumption and utilization in health care. It is measured in terms of economic value of the finished products and from this quantification it is possible to make comparisons in economic terms. However, it should be pointed out that "economic" value of medicinal products is not synonymous of "health" value and also that there are considerable variations in the cost and price structures in different countries. Therefore, comparison of economic data alone may be misleading.

3.7 The global output of world production of manufactured medicinal products for human use was estimated in 1976 at approximately US \$ 50 billion at manufacturers' prices. Industrialized countries accounted for about 90 per cent of the output. Out of the remaining 10 per cent, three developing countries (Brazil, India and Mexico) accounted for 5 per cent.

3.8 It appears, from market surveys, that in economic terms the developed countries account for more than 80 per cent of the world pharmaceutical consumption and the developing countries for less than 20 per cent, with about 15 per cent of the world population accounting for 55 per cent of the global consumption. The breakdown of the estimates of global consumption for 1976 is as follows:

|          |       |         |       |
|----------|-------|---------|-------|
| Europe   | 45.8% | Africa  | 2.42% |
| Americas | 26.9% | Oceania | 1.14% |
| Asia     | 23.7% |         |       |

3.9 The international trade of medicinal and related products in 1974 was, according to the United Nations statistics, as follows in millions US\$:

|                      | Imports | % of world imports | Exports | % of world exports |
|----------------------|---------|--------------------|---------|--------------------|
| World trade          | 6 042   |                    | 5 910   |                    |
| Developed countries  | 4 052   | 67.1               | 5 486   | 92.8               |
| Developing countries | 1 990   | 32.9               | 424     | 7.2                |

It appears, from the same source of statistics, that five industrialized countries accounted for 64 per cent of the world export of medicinal and related products.

The growth of the world pharmaceutical market, currently estimated at 10 per cent per year in economic values, is determined by three main factors:

- expansion of health care coverage to larger segments of the population;
- price increase effect of moving from older, less expensive medicinal products to new, research-based, more expensive products (changing prescription habits);
- price increases of existing products.

3.10 In developed countries, generally 5-8 per cent of GNP is spent on health care; during the past decade, health care expenditure has increased at a more rapid rate than GNP. Expenditure on pharmaceuticals represents 10-20 per cent of the total health expenditure. In developing countries figures vary widely, but the pharmaceutical expenditure per capita/per year may be below US\$ 1 and may be as high as 50 per cent of the total health care expenditure. The high proportion of the health budget spent on medicinal products in many developing countries may be due to various factors such as:

- finished products or intermediates are imported and are often paid for in convertible currencies without the countries having the capability to obtain the best suitable products under the most favourable conditions;
- the non-pharmaceutical components of health care expenditure are relatively inexpensive as few sophisticated hospitals exist and the salaries of health personnel are low in comparison to developed countries;
- the lack of organized health care to the whole population leads to a demand for medicinal products unrelated to other aspects of health care.

In spite of the high proportion of the health care budget spent on pharmaceuticals, it has been estimated that in many developing countries 60-80 per cent of the population, mainly in rural areas, do not have constant access to even the most essential drugs.

In developing countries, vaccines and drugs against infections and parasitic diseases, medicines for maternal and child health care and preparations to treat common illnesses are vital elements in health care. Pharmaceuticals, however, are expensive items in these countries and their use must, therefore, be planned carefully to optimize the benefits of expenditure in terms of health benefits; unnecessary pharmaceuticals could otherwise become a wasteful drain on a developing country's scarce resources for health care.

3.11 The gap between developed and developing countries in production and trade in pharmaceutical products is creating, in most developing countries, ever-increasing technical, financial and social problems in meeting the growing needs and demands for medicinal products related to the extension of organized health care to larger segments of the population. The less developed countries, having a GNP of around US\$ 200 per capita/per year, find it increasingly difficult to afford certain essential products at unit prices which are equal to or even higher than in the developed countries which have a GNP of around US\$ 4 000. In most cases, these must be paid for in scarce convertible currencies. Most developing countries, having established local production from imported raw materials or intermediates (formulation of finished medicinal products), are still dependent on expensive foreign materials, equipment, capital investment, technology and management.

3.12 The world structure of the pharmaceutical industry is extremely complex and it is almost impossible to summarize the situation. The pharmaceutical industry occupies a unique position in the scope and depth of its operations in international markets. On the world markets, a limited number of major producers are significant in terms of international participation; a few developing countries, having a well developed pharmaceutical industry, are increasingly participating in international trade. However, pharmaceutical innovations are mainly developed by transnational corporations which, by pooling capital, technology and modern management on an international scale, have been able to continue to develop new products and to market them on a world-wide scale in spite of stringent regulatory controls in the industrialized countries and the increasing costs of drug research and development. It is estimated that the development of a new product having an impact on the international market may require 5-10 years and an investment of several millions of US dollars.

#### 4. MEDICINAL PRODUCTS AND "ESSENTIAL DRUGS"

4.1 In the report by the Director-General to the Twenty-eight World Health Assembly, reference was made to the experience gained in some countries where schemes of "basic" or "essential" drugs had been implemented to extend the accessibility of the most necessary medicinal products to the people whose basic health needs could not be met by the existing pharmaceutical supply system. In resolution WHA28.66, the Health Assembly requested the Director-General inter alia to advise Member States on the selection and procurement, at reasonable cost, of essential drugs of established quality corresponding to their national health needs.

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<sup>1</sup> WHO Official Records No. 226, 1975, Annex 13, pp.96-110

4.2 The report of the WHO Expert Committee on the Selection of Essential Drugs<sup>1</sup> contains proposed guidelines for establishing a list of essential drugs, suggestions for drug information and educational activities and a "model" list of essential and complementary drugs which can furnish a basis for countries to identify their own priorities and to make their own selection. This list should be regarded as a contribution to solving the problems of those Member States whose health needs far exceed their resources and who may find it difficult to initiate such an endeavour on their own. The Executive Board, at its Sixty-first Session, having reviewed this report, requested the Director-General to continue to identify the drugs and vaccines which, in the light of scientific knowledge, are indispensable for basic health care and disease control in the vast majority of the population, and to update periodically this aspect of the report.

4.3 In recent years, many medicinal products have been marketed with little concern for the differing health needs and priorities of different countries. Promotional activities of the drug manufacturers have created a demand greater than the actual needs. It is clear that for the optimal use of limited financial resources, priority should be given to the availability of those medicinal products of proven efficacy, acceptable safety and suitability to satisfy the health needs of the majority of the population. Thus, the concept of "essential drugs", linking drug priorities with health priorities, implies a continuing process of product selection, taking into account financial resources, changing priorities for public health action and epidemiological conditions, as well as progress in pharmacological and pharmaceutical knowledge. The selected drugs are called "essential drugs", indicating that they are of the utmost importance, and are basic, indispensable and necessary for the health needs of the population.

4.4 The preparation of a list of essential drugs of uniform general applicability and acceptability is not possible because of the great differences among countries with regard to the pattern of prevalent diseases, the type of health personnel available, financial resources, and genetic, demographic and environmental factors. Therefore, the extent to which countries implement schemes or establish lists of essential drugs is a national policy decision and each country has the direct responsibility of identifying its own priorities according to national health and drug policies.

4.5 The process of selection of essential drugs should be dynamic and flexible to avoid a rigid approach which could be counter-productive. A limited list of drugs may not provide for the needs of every person, but should certainly meet those of the vast majority. It should be clear that the exclusion from a list does not imply rejection or that no other drugs are useful, but simply that, in a given situation, those drugs are the most needed and should be available at all times in adequate amounts and in the proper dosage forms. The selection should be based on adequate scientific data obtained in controlled clinical trials and/or epidemiological studies.

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

4.6 The notion that the number of necessary drugs is relatively small is supported by experience in both developing and developed countries where limited lists and formularies are successfully used, for example, in hospitals. Limited drug lists have several advantages, particularly in developing countries:

- reduction in the number of medicinal products to be purchased, stored, analysed and distributed;
- improvement in the quality of drug utilization, management, information and monitoring;
- stimulation of local pharmaceutical production.

An effective programme of drug selection, coupled with appropriate information and education, may help to improve attitudes to the role of drugs in health and disease, and health care in terms of both effectiveness and economy.

4.7 The range of medicinal products marketed in various countries varies from more than 30 000 to less than 2 000. The figures refer to dosage forms in a particular strength from a particular manufacturer and not to the active substances they contain and do not include herbal remedies. From the point of view of the "health needs"<sup>1</sup> of the majority of the population, three main types of medicinal products can be considered, although it is recognized that the distinction is not clearcut and may not apply in every situation:

- essential drugs or priority medicinal products used on the basis of scientific and clinical data;
- complementary drugs<sup>2</sup> or medicinal products to complement a list of essential drugs;
- remedies used on the basis of long experience, but for which adequate scientific and clinical data is being accumulated.

<sup>1</sup> "Health needs" are described as scientifically (biologically, epidemiologically) determined deficiencies in the health of the population. Essential and complementary drugs can prevent or influence a health condition in a predictable fashion and can be considered as efficacious and safe if properly used because their expected risks and benefits in specific indications have been evaluated on the basis of adequate scientific and clinical data.

<sup>2</sup> These drugs provide: (a) treatment in rare disorders; (b) alternatives when infectious organisms develop resistance to essential drugs; (c) special pharmacokinetic properties, etc.

4.8 In both developed and developing countries, there are numerous medicinal products, used for minor or self-limiting illness, psychosomatic and physiopathological disorders, for which scientific and clinical data are being accumulated. Most of these products are standard formulations or contain substances of natural origin, have high consumer approval and can be considered safe on the basis that toxic effects have not been recorded during long-term and widespread use. As long as adequate clinical data are not available, they cannot be considered as essential or complementary drugs. As health care in different countries is influenced by cultural factors and medical tradition, the choice and use of this type of medicinal products vary accordingly. In certain developed countries, these products were submitted to systematic review and, when criteria for proven effectiveness were not met, the products were withdrawn from the list of products paid for or reimbursed by social security. In developing countries medicinal products of this type are often imported from the industrialized countries; countries aiming at self-reliance produce them locally from natural resources, particularly medicinal plants (see section 5.11).

4.9 The WHO Expert Committee on the Selection of Essential Drugs<sup>1</sup> pointed out that in a number of countries, large segments of the population do not have ready access to health facilities, which tend to be oriented predominantly towards hospitals and urban areas. In an attempt to strengthen the health care system and achieve maximum population coverage with low-cost but effective and efficient health services, attention is being focused increasingly on the development of primary health care. This approach involves the use of health workers with minimum formal training to perform limited tasks at the community level.

4.10 Consequently, there is a need to identify the widest range of drugs that can be safely and adequately handled by this type of health worker. This implies the development of guidelines for further limited selection for primary health care from the list of essential drugs. Since there is a wide variation between countries in the quality and capabilities of primary health care workers, in drug policies and in disease prevalence, the Expert Committee felt that it was impossible to prepare such a sublist, desirable as it would be. Therefore, the selection of drugs for this list should be made at the local level with whatever guidance WHO can provide.

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5. TECHNICAL AND ADMINISTRATIVE COMPONENTS OF DRUG POLICIES AND MANAGEMENT OF THE PHARMACEUTICAL SUPPLY SYSTEM

5.1 Usually the technical and administrative components of drug policies and management of a fully developed pharmaceutical supply system are as follows:

- drug legislation and regulatory control (5.2)
- product selection (5.3)
- quality assurance (5.4)
- procurement (5.5)
- local production (5.6)
- distribution (5.7)
- pricing (5.8)
- information, utilization surveillance and training of health workers in the proper use of drugs (5.9)
- research and development (5.10)
- utilization of locally available natural resources for health care (5.11)
- self-medication (5.12)

The above components are briefly analysed in the following sections, with emphasis on problems encountered in developing countries.

5.2 Drug legislation and regulatory control

5.2.1 Legislation gives authority and responsibility to the government, or to designated public agencies, for the control of the different components of the pharmaceutical supply system. Drug legislation and regulatory control are different in different countries and usually cover the following aspects:

- registration of medicinal products
- licensing of importation and/or importers
- licensing of domestic manufacturers and distributors
- control of foreign investments and loans
- control of transfer of technology
- control of industrial property and patents
- control of prices and pricing system

- control of marketing practices such as advertising, information, promotion through medical representatives and free samples' distribution, etc.
- control of the quality of marketed products and inspection of manufacturing plants for compliance with good manufacturing practices
- control of labelling of the products, including use of generic names
- surveillance of marketed products, including monitoring of adverse reactions

5.2.2 To implement regulatory control on all marketed medicinal products, responsibility to issue guidelines, norms and administrative regulations is frequently assigned to a regulatory drug control agency or to a department of the ministry of health. Depending on the centralized or decentralized structure of the country, administrative responsibilities are shared in variable proportion by central, regional and provincial authorities, although general norms and regulations are issued by the central authority. Other components of the pharmaceutical supply system may be subject to control, such as prices. In some countries, appropriate legislation gives the government responsibility for developing local pharmaceutical production and/or export capabilities and for foreign capital investment in the pharmaceutical sector; in such cases, legislation for industry and trade development should not be in conflict with the objectives of health legislation on domestic drug control and pharmaceutical services. The licensing of pharmacists and pharmacies is also regulated in many countries by appropriate legislation.

5.2.3 Legislation concerning social security or national health insurance schemes may contain provisions related to medicinal products such as limited lists of reimbursable products, maximum allowable costs, procurement, etc. Problems of coordination with legislation concerning regulatory control may arise as well as problems of coordination among the different authorities responsible for implementation.

5.2.4 The implementation of drug legislation is a highly complex matter, especially for developing countries where only limited and scattered financial, technological and human resources are available. In many developing countries the following could be considered as priority areas requiring appropriate legislation:

(a) Drug control

- procedures for the selection of essential drugs for health needs and strengthening of quality control of these products
- use of generic names whenever possible
- registration (or licensing) of pharmaceutical products on the basis of evaluated information obtained through regional agreements or from international organizations, particularly WHO



- control over importation, production, distribution and advertising of drugs

(b) Development of drug production

- incentives for development of local production
- regulation of foreign investment in the pharmaceutical sector
- adequate regulation of elements of industrial property, such as patents and trade names

(c) Pharmaceutical distribution

- regulations on multisource international procurement (e.g., tenders), especially in the public sector
- legal definition of drug distribution within the country, giving clear responsibility to each level of the network, i.e., central, regional, subregional and peripheral

As pharmaceuticals move internationally, there is need for cooperation among the authorities of the countries at the regional or subregional level in the field of drug legislation and for information exchange on manufacturing practices, drug prices, and registration of new drugs.

5.2.5 Greater involvement of national administrations in the drug field also raises the legal question of product liability. Product liability generally rests with the pharmaceutical manufacturers, but when distributors and retailers are different from the manufacturers, the sharing of the liability raises difficult problems. Also, when the state manufactures and distributes drugs, its liability for the products should be defined.

5.3 Product selection

5.3.1 As drugs and vaccines are major strategic components in preventive and curative health action, it is obviously necessary to draw up a list or lists of priority drugs which can be available routinely at the different levels of health action. The country's resources being generally limited, any kind of health action necessitates the setting of priorities. When the health needs of the country are not, or cannot be, satisfied by private practice or the free market, public health action is required.

5.3.2 The other reason for selecting a group of drugs is the limited economic resources and availability of managerial skills when the government assumes responsibility in pharmaceutical supply. The price decreases when large quantities of a limited number of drugs are purchased. Physicians in private practice prescribe generally 50 to 100 products, according to the demands of patients, the local epidemiological pattern, their specialization and product availability. Therefore, in private medical practice, the physician himself selects a limited number of products according to the situation in the particular area where he practices. In organized health care, the

selection is based on prevalent health needs of the community, taking into consideration safety, efficacy, quality and economy of products.

5.3.3 The report of the WHO Expert Committee on the Selection of Essential Drugs<sup>1</sup> (see section 4.2) contains criteria 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. The report suggests that the selection should be entrusted to a national committee, including individuals competent in the field of clinical medicine, pharmacology and pharmacy, as well as peripheral health workers.

5.3.4 Drug selection should be based on the results of benefit and safety evaluations obtained in controlled clinical trials and/or epidemiological studies. The international nonproprietary (generic) names should be used whenever possible. Regulations and facilities should be available to ensure that the quality of selected medicinal products meets adequate quality control standards, including stability and, when necessary, bioavailability. Cost represents a major selection criterion. In cost comparisons between drugs, the cost of the total treatment, and not only the unit cost, should be considered. Preference should be given to therapeutically equivalent products for which local, reliable manufacturing facilities exist. The list should be reviewed at least once a year and new drugs should be introduced only if they offer distinct advantages.

5.3.5 The real drug needs can either be qualitative (the type of drugs) or quantitative (the amounts) and it is necessary for all countries to be able to identify these needs. Clinical pharmacological expertise, epidemiological surveys and drug utilization surveys are essential tools in determining such needs. In ensuring that such tools are used effectively, there is an urgent need for developing countries to develop, either alone or with WHO cooperation, a sound health information system.

5.3.6 The main difficulty in product selection and in the determination of quantities required lies in effective coordination among various health services, such as hospitals, community or rural health centres, campaigns for the control of specific diseases, such as malaria, tuberculosis, leprosy, etc., and for population control. Furthermore, in a decentralized health care system, there are problems of coordination among the central, intermediate and peripheral levels.

#### 5.4 Quality assurance

5.4.1 Ensuring the quality of drugs to be provided to the population is the responsibility of the government and the producers. Quality specifications to which drugs and vaccines must conform are established by national or international organizations and are described in national or international pharmacopoeias.

5.4.2 The division of responsibility between the government and the producers to ensure the quality of drugs and vaccines varies from country to country. The necessity for control both by the government and by the producers themselves is generally recognized.

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

Government responsibility in quality assurance covers the following main areas: (a) inspection of manufacturing establishments, stores and pharmacies; (b) sampling and analysis in national control laboratories; (c) verification of analytical specifications for drugs not included in official pharmacopoeias; (d) use of the Certification Scheme.<sup>1</sup>

The manufacturer's responsibility for the quality of the drugs he produces includes, (a) conducting self-inspection at all stages of production; (b) providing adequate analytical facilities; (c) keeping records of all analytical tests performed, and of all decisions on the release of products.

5.4.3 The responsibilities of distributors and pharmacies vary from country to country and should be defined according to local conditions.

5.4.4 Manufacturers' specifications are sometimes more detailed than those of official pharmacopoeias. There are often legitimate reasons for this approach, i.e., to ensure that drugs meet official specifications during their entire shelf-life. Purity requirements that increase the cost of the drugs without contributing to drug safety should be avoided. Drugs produced in a country where there is a strict regulatory control of quality, efficacy and safety are generally believed to be better drugs. Exaggerated claims of high quality may not be related to better therapeutic performance of the product but are sometimes used to justify higher prices and to increase market power

5.4.5 In developing countries, the government often cannot afford to build up a complete quality control system and producers, when they exist, cannot follow entirely the same good manufacturing practices as the developed countries. The extent to which good manufacturing practices are implemented depends on financial and technical resources and on the type of drugs produced.

5.4.6 In many developing countries, most pharmaceutical products are imported and the conditions of distribution, storage and utilization differ from those of developed nations. Therefore, it would be worthwhile to consider certain strategies in the following fields to meet the needs of such countries:

(a) Effective use of the Certification Scheme<sup>1</sup> as approved by the World Health Assembly in resolution WHA28.65. At the present time the following countries have agreed to participate in the Scheme:

Argentina, Australia, Belgium, Brazil, Cyprus, Denmark, Egypt, El Salvador, Finland, France, Iceland, Iran, Italy, Japan, Jordan, Mauritius, New Zealand, Norway, Poland, Portugal, Republic of Korea, Romania, Senegal, Spain, Sweden, Syrian Arab Republic, Thailand, Tunisia, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland, United States of America.

(b) Exchange of information among the countries on pharmaceutical inspection, and agreement on mutual recognition of inspection among the countries.

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<sup>1</sup> Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce, Supplement to WHO Chronicle, 1977, Vol. 31, No. 12

(c) Sampling of incoming drugs, their analysis through technical co-operation among the countries, and exchange of information on products and prices.

(d) Development of "basic tests" for the analysis of the products at the distribution and utilization sites. They provide simple means for verifying the identity of the drug and ascertaining the absence of gross degradation. Such tests could be used in situations where large and well equipped laboratories are not available.

(e) Because of specific climatic conditions (temperature and humidity) and transportation conditions, the requirements for stability of product and packaging materials established in industrialized countries do not satisfy the quality assurance of products in many developing countries. The requirements for stability should be established for use in developing countries by joint collaborative efforts among the countries.

## 5.5 Procurement

5.5.1 Many countries are diversifying their procurement sources within the context of self-reliance. This policy usually gives priority to procurement for the public sector. As pharmaceuticals are an important part of public purchases and are amongst the most "needed" commodities for the country, the establishment of a procurement system from multiple sources of supply (domestic or international) by government or public agencies is a priority where economic resources are limited. For effective procurement only a relatively small qualified staff is required if the necessary "marketing intelligence" and quality assurance system are available, and thus substantial sums of public money may be saved.

5.5.2 "Marketing intelligence" is the most needed tool for procurement and represents the country's "bargaining power". It is obtained mainly by continuing survey and analysis of:

- (a) Producers and their manufacturing practices and production scale.
- (b) Price trends and early detection of speculation and other malpractices.
- (c) Reliability of quality assurance, e.g., through batch certificates and control.
- (d) New drug information, especially registration status in the country of origin.
- (e) Information on product interchangeability, taking into consideration bioavailability and therapeutic equivalence.

5.5.3 In several developing countries, a well organized procurement system, based on world-wide tender, has been established as one of the major activities of the ministry of health. The system includes facilities for storage with cold room, packing, repackaging, transport, basic quality control and often production of galenicals, e.g., powders,

ointments, solutions and elixirs. The administration usually consists of professionals, general service, accounting and statistical staff. Usually, the agency procures not only drugs and vaccines, but also other medical equipment and materials.

5.5.4 Procurement procedures are based on tenders and, for specific drugs, on price negotiation under the responsibility of an independent committee of officials from each ministry - health, trade and finance, including customs. The special allocation of hard currency, exemption from customs duty and tax, and collective assurance by the government are also matters of importance when establishing a procurement agency.

5.5.5 The first step to be taken in building up a procurement agency is to draw up a list of drugs to be procured according to the needs of the health services (basic or essential drug list) and estimates of the quantities required (annually, bi-annually or quarterly). Ideally, the estimates of items and quantities should be based on the health information available, taking into consideration allocations available from the health budget. However, in many developing countries, this cannot be done in the initial phase owing to incomplete health information and to particular types of disease patterns, such as mixed infections, plus malnutrition. Therefore, estimates are usually based on the actual demands of the health services, corrected and re-evaluated through inventory control and utilization surveys. Estimates are easier in the case of a specific disease control campaign.

5.5.6 Ideally, in order to reduce the price of drugs, products should be bought in bulk and repackaged in the country with standardized packing and labelling, taking into account the necessity for clear distinction between different drugs and their strengths. However, to undertake such activities, the procurement agency requires specialized technical staff for packing, stock-keeping and quality control and premises for storage and packing, which might increase the total administrative costs.

5.5.7 The unit price of drugs could be considerably reduced by ordering in large quantities. Therefore, tenders should be made annually, or at long intervals, for products which have a long shelf life and whose international price is stable. The procurement of patented products, or products produced by a few manufacturers, requires price negotiation. Here "marketing intelligence" is greatly needed.

5.5.8 In principle, products should be procured under their generic names. However, procurement methods vary according to the following three major categories of drugs: (a) drugs well protected by patent and produced by only one manufacturer or by licensed manufacturers; (b) generic drugs which are produced by only a few manufacturers; and (c) generic drugs which are produced by many manufacturers.

5.5.9 The main technical obstacles, other than "marketing intelligence", for the national procurement agency in developing countries are: (a) lack of managerial skills, especially in price/quality evaluation; (b) lack of hard currencies; (c) trade regulations and trade agreements with particular countries; (d) tenders may not reach international suppliers; and (e) quality assurance.

5.5.10 The problem of quality assurance can be solved partially by requiring product certificates according to the WHO Certification Scheme (see section 5.4.6). Batch certificates are usually issued by the manufacturers, although some governments deliver such certificates, for example, for antibiotics. However, quality control of goods arriving in developing countries would require technical cooperation with laboratories in other developing countries as well as with laboratories in the developed countries.

5.5.11 Many of the procurement problems could be resolved through technical cooperation among developing countries and with international organizations such as WHO, which could play a greater role in coordinating and cooperating in the necessary transfer of technology, information, managerial skills, etc. Cooperation among developing countries in drug procurement could considerably build up "bargaining power", stimulate competition among suppliers and could lead to more favourable conditions in the purchase of medicinal products.

## 5.6 Local production

5.6.1 There are three main types of pharmaceutical production (see section 3.1): repackaging of finished products bought in bulk, formulation from imported and/or locally available raw materials and production of raw materials. The feasibility of building up viable pharmaceutical production, with the aim of self-reliance in pharmaceutical supply, depends on many factors such as, (a) population size and per capita income; (b) available technical manpower and supporting infrastructure; (c) geographical and climatic conditions; (d) water and energy supplies; and (f) the distribution network.

5.6.2 These factors are often major constraints and, in many cases, all the drugs needed cannot be produced economically in one country. Ideally, therefore, cooperation is required among the countries themselves. In the long run, the countries will need at least a basic formulation factory with a view to preventing difficulties of supply due to any unforeseen political and economic events, and to making themselves as independent as possible. Before deciding to establish formulation factories, long-term planning is required, taking into account the health needs of the population and available financial and technological resources. Whether the essential drugs are produced by a government factory under the responsibility of the ministry of health, or the ministry of industry, or by private industry, from which the ministry of health can buy the products at reduced price, is a matter of local conditions and of the socio-political structure of each individual country. In the public sector, it is important to establish local production according to a list of essential drugs, and to ensure that the products supplied meet adequate standards of quality.

5.6.3 As the pharmaceutical production should meet the priority health needs, a preliminary feasibility study should be conducted in order to identify the health needs before the industrial feasibility study is undertaken. This preliminary feasibility study is also very important for fund-raising when multilateral or bilateral assistance is required. After analysis of the preliminary feasibility study, based on the annual requirements for each type of formulation (tablets, ampoules, sterile products, intravenous fluids, syrups, powders, elixirs, ointments, ear or eye drops, etc.), the following step can

be undertaken, i.e., industrial feasibility study, including (a) type of building and space; (b) type and amount of equipment; (c) number and type of experts and training of technical staff; and (d) quantity, grade and cost of raw materials, including packaging materials. The industrial study should include an assessment of capital investment required, annual running costs and mode of financing (domestic, bilateral, multilateral).

5.6.4 The development of local pharmaceutical production should proceed sequentially, beginning with the simpler activities of repackaging and formulation and steadily moving towards more complex activities, requiring transfer of technology from industrialized countries. Owing to policies and strategies of the major pharmaceutical industries, and to the continuing progress in pharmaceutical technology, such transfer is often difficult and only partial transfer of technology is usually achieved.

5.6.5 The establishment of local production of vaccines requires a separate feasibility study and the following development sequence towards self-sufficiency in the provision of vaccines could be considered:

(a) The establishment of a specialized quality control laboratory<sup>1</sup> to check the quality of imported vaccines and to verify that they have maintained their potency throughout their storage period. Furthermore, such a facility could measure the antibody response of the community to vaccines and, therefore, measure the efficacy of immunization programmes.

(b) The establishment of a diluting, filling and packaging facility in order that vaccines may be imported in bulk in the concentrated form. Such vaccines can be stored refrigerated in this form for several months prior to diluting, blending and filling. Before this facility can be established, it is necessary to have a quality control facility in order to test the products in the final form.

(c) The implementation of stages (a) and (b) will provide data to the health authorities on which to base a decision concerning the establishment of a national vaccine production unit and to build up experience of the staff in filling and quality control which will be invaluable in vaccine manufacture.

5.6.6 The breakdown of the costs of vaccines has revealed that 80 per cent of the final cost is involved in ampouling and packaging, compared to 20 per cent in the production of the vaccine in bulk form. A further breakdown has revealed that of the 20 per cent of costs involved in producing the bulk vaccine, 60 per cent applies to quality control and 40 per cent (7 per cent of total cost) to producing the bulk vaccine. Although these figures differ from country to country, they indicate that in many developing countries savings could be made by importing vaccines in bulk and by processing the vaccines locally in final form.

5.6.7 Thus, the first step in developing local production of vaccines is the establishment of a quality control facility, then moving towards vaccine production. For countries already making vaccines, but not having quality control, it is urgent to rectify this situation because it is unwise to assume that

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<sup>1</sup> WHO Technical Report Series, No. 444, 1970 - "Development of a National Control Laboratory for Biological Substances"





- adequate storage facilities
- adequate inventory control
- sufficient and appropriate transportation facilities and maintenance service
- packing material - standardization and labelling
- quality surveillance
- education and regular training of staff
- drug utilization surveys

Pharmaceutical stores often use the obsolete "indent system", whereas a change in management to inventory control and forecasting would considerably improve the efficiency and distribution and would save goods and money.

5.7.4 The major requirement in establishing successful distribution systems is the education and training of personnel dealing with drug distribution, such as administrative staff, inspectors, accountants, storekeepers, packers, transporters, pharmacists, dispensers, etc. Such personnel should be conscious of the fact that they are handling goods most "needed" for the health of the people and that they are participating in the health action of the country. These educational activities will prevent wastage and leakage of valuable drugs during distribution and will improve the utilization of drugs for health care. Periodical seminars, workshops and meetings on drug management will be the key factors in improving drug distribution.

## 5.8 Pricing

5.8.1 The prices of drugs are generally determined either by cost calculations or by market situations.

When determining the prices of drugs by cost calculation, the following expenditures are usually considered:

(a) cost of production, including production of raw materials, formulation, packaging, quality assurance, research and development (comprising royalties for patents and know-how), marketing (comprising advertising, direct and indirect sales promotion), general administration and returns of investment;

(b) cost of distribution, including storage, transportation, sales promotion, client services and general administration;

(c) cost of dispensing, including technical, administrative and storage expenses, as well as miscellaneous expenses for consumer services.

A variable amount of profit and taxes is added to these costs.

The main components of the above-mentioned costs could be determined in fixed amounts or as a percentage of the price, within acceptable limits. However, the most difficult components in determining the prices of drugs are the costs of production of raw materials and especially the cost of active ingredients which are generally known only to the producer. Such costs are the most important factors in determining the prices of drugs by cost calculation because the pricing system is generally based on a percentage mark-up of raw materials' costs.

The prices of drugs can also be determined according to the market situation, i.e., the size of the demand for a particular product, the prices of competitive products and the therapeutic advantages of a new product over the existing ones.

5.8.2 The drug companies determine different prices of their products in each country, or even in each district, taking the above-mentioned factors into consideration. As drugs are moving internationally, many transnational companies decide on the transfer of prices according to their own interests. Generally, when a country formulates national policies for drug production, procurement and distribution, and sets up regulations on drug pricing, the prices of drugs tend to decrease.

5.8.3 In some countries, the government does not fix the prices of individual drugs but it expects that the prices of drugs will decrease through fair trade practices in free competition among the different companies. However, because of the oligopolistic structure of the pharmaceutical industry, the prices of drugs are not always brought down as expected. Nevertheless, as pharmaceuticals are not considered as ordinary commodities, the governments generally concentrate their efforts mainly on regulating the prices of selected drugs for the public sector, for example, health services. In this case, the evaluation of "relative efficacy", "cost-benefit" and "acceptable quality" are the most important technical components for determining such prices.

5.8.4 Awareness of the cost of health, especially of the cost of drugs, by health workers, but also by consumers, is rapidly increasing. In response to this situation, governments and public agencies should establish adequate communication on "prescribing costs" because reducing the unit price of drugs is not enough to achieve savings on drug expenditure. Furthermore, the final objective of reducing drug prices is to extend the access of the population to more useful drugs.

5.8.5 Drug prices in a country often reflect the government's drug policy and its involvement and participation in pharmaceutical expenditure. When studying the structure of drug prices, three levels should be considered:

- (a) importation of finished pharmaceutical products;
- (b) production of finished pharmaceutical products;
- (c) importation of raw materials (active substances and intermediates) for local production (formulation)

In a Consultation on Essential Drugs Prices Trend in Developing Countries<sup>1</sup>, held in Geneva in 1977, the crucial role that national drug policy plays in drug prices was recognized. Recommendations were made to encourage technical cooperation among developing countries on a regional or interregional basis in establishing an information system on drug prices and pricing systems through the assistance of WHO.

5.8.6 Pricing of medicinal products is perhaps the most controversial component of the pharmaceutical supply system because it encompasses the complexities of all the others. There is a wide range of opinion about what a reasonable price would be and there are such wide price variations from country to country that often they cannot be explained in the light of economics only. In the absence of a sound formula for price calculations, different methods are applied in price controls and it is not always easy to determine the degree of success achieved or the implications on other components of the pharmaceutical supply system, for example, on research and development.

5.8.7 Usually, the cost of pharmaceutical products to governmental health services is quantified in terms of the prices at which the products are purchased. However, it is important to note that within the pharmaceutical supply system other sectors of the government influence the cost-price relationship by fixing customs duties, direct sales taxes and indirect taxes on production, distribution and dispensing. The total of these charges are passed on to the consumer or his financing agent (in most cases the government itself). Thus, the relationship between cost and price of medicinal products requires a careful analysis of the role of different sectors of the government involved and multisectoral solutions within national drug policies. It appears that in many cases such policies are not clearly formulated and drug prices are a free-floating factor within the context of health expenditure.

#### 5.9 Information, utilization surveillance and training of health workers in the proper use of drugs

5.9.1 Drugs should be accompanied by up-to-date and objective information on the potential benefits and risks associated with their use. The type of information on drugs that is needed varies according to the users: policy-makers, decision-takers in the regulatory authorities, procurement officers, pharmacists, distributors and, finally, prescribers and consumers. Information on chemical and pharmaceutical, pharmacological, clinical and some economic aspects is generally available, whereas basic information of a technological and economic nature on a particular product is considered as industrial and intellectual property and is therefore not released.

5.9.2 Information on the safety of drugs is an essential component of drug information for regulatory authorities, prescribers and consumers. In several developing countries most of the information on drugs has been supplied by the drug companies in the form of booklets, pamphlets and visits by detailmen. This information is often biased and promotional in nature. Governments are taking the responsibility for evaluating and controlling advertisements and other information on drugs for prescribers and consumers

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<sup>1</sup> Unpublished document, DPM/78.1

and should ideally publish their own data sheets, information notices, booklets, etc., on a regular basis. However, in developing countries there is often a lack of qualified staff and economic resources to successfully provide timely, objective and evaluated information.

5.9.3 Several developing countries have National Drug Formulary Committees which, in addition to advising on the selection of essential drugs, also prepare regular information sheets. Various types of information are needed by prescribers and consumers to obtain optimal utilization of drugs. In the report of the WHO Expert Committee on the Selection of Essential Drugs<sup>1</sup> a drug information sheet, adjustable to the needs of the prescribers, is given as a model.

5.9.4 As there is a scarcity of qualified manpower, financial resources and technical infrastructures in most developing countries, technical co-operation among countries in the adequate transfer of drug information, supported by WHO, would be the most appropriate solution.

5.9.5 The dissemination of drug information should be combined with educational and training activities on the proper use of drugs for prescribers and consumers. Education of health professionals about drugs should begin early in their training and should be continuous, not only throughout their formal training period, but throughout their entire professional life. In addition to the information included with each product, information could be disseminated through regional training seminars, articles in medical journals and newsletters. To minimize bias, it will probably be necessary for these educational efforts to be supported by the government. Education of the consumer is particularly important at the primary health care level where a significant proportion of drug usage will be in self-medication.

5.9.6 Health authorities are paying greater attention to surveys of drug utilization, not only consumption figures but also utilization patterns, including consumer acceptance of both modern and traditional drugs. Such surveys are an important source of information for formulating and reviewing national drug policies. The objective of a drug utilization survey is to quantitate the present state, developmental trends and time course profiles of drug usage. This type of data can then be used: (a) to measure the effects of informational and regulatory measures, price policy, etc.; (b) to define areas for further investigation on the absolute and relative efficacy and safety of drug therapy; (c) to aid in the determination of benefit/risk and cost/effectiveness; and (d) when properly interpreted, to indicate the overuse, underuse, or misuse of single drugs or therapeutic classes. A continuing drug utilization surveillance, carried out by health workers and coordinated at the central level, would provide the most useful information for drug management and also for the prevention of drug abuse.

5.9.7 Valuable information on drugs is in the hands of the manufacturers. It is an important social responsibility of the pharmaceutical industry to collaborate with governments in providing unbiased and accurate drug information to meet the health needs of the populations.

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

## 5.10 Research and development

5.10.1 Research and development of modern pharmaceutical products is a technological endeavour dependent upon four interrelated areas - basic research, applied research, the development of investigational products for preclinical and clinical testing and the ongoing production of marketed products.

5.10.2 Modern pharmaceutical research led, over the past decades, to the development by the pharmaceutical industry of many products widely used in medicine and public health. This progress has resulted from a few breakthroughs, followed by the development of a long series of related compounds, most of which never reached the market but some, by incremental improvement, proved to be extraordinarily valuable.

5.10.3 Drug research and development is an integral part of national drug policies and of the pharmaceutical supply system; priorities should be established taking into account the health needs of the country and the objectives for economic development, including competitiveness of exported products on international markets. Research and development in the field of modern pharmaceuticals is a major part of health and industrial technology and is carried out by the pharmaceutical industry with the direct or indirect support of the public sector in academic or governmental research institutes and the training of research workers. Despite national will to develop drug research and development as a part of scientific and technological progress, it is almost impossible for most developing countries to follow the pattern of the industrialized countries because of the lack of the necessary infrastructure, manpower and economic resources.

5.10.4 In the developed countries, the efforts of the pharmaceutical industry are often concentrated on the research and development of sophisticated products and technologies in order to create or maintain leadership in a highly competitive marketing environment. This situation leads to an increase in the number of drugs, many of which are not relevant to the real health needs of developing countries and are too expensive for them. In most countries, patents and proprietary (brand) names of products are considered as incentives to engage in research and development and constitute an important part of the marketing power of the major pharmaceutical enterprises operating internationally through licensing agreements.

5.10.5 The percentage of research and development costs included in the price of products varies from 5 to 20 per cent. The research-based pharmaceutical industry, which makes a high contribution to progress in medicine, invests considerable resources in drug research and development and is likely to continue to do so in order to maintain competitiveness, as long as it can make sufficient return on capital investment. Because of the increasing involvement of governments in meeting the health and pharmaceutical expenses, the question of the orientation of drug research and development has been raised. At the international level, a matter of concern is the trend in most research-based pharmaceutical industries to diminish investments in research and development in the field of tropical diseases, which are of little importance in the industrialized countries. The promotion of collaboration of the research-based pharmaceutical industry with developing countries is urgently needed,

duly supported by governments and international organizations, in a joint effort to reorient drug research and development more in line with the most pressing health needs of the world's population.

5.10.6 In developing countries, there are other priority areas for research and development which could be considered: (a) clinical, chemical and biological research on the therapeutic properties of locally available resources of natural origin; (b) development of appropriate technologies for the identification, collection, specification and processing of medicinal plants; (c) research on the logistic and technological aspects of pharmaceutical supply, for example, the cold chain for vaccines; and (d) development of technologies for the formulation and packaging of stable and effective dosage forms suitable for local conditions and, whenever possible, for the production of raw materials, especially those which are locally available.

#### 5.11 Utilization of locally available natural resources for health care

5.11.1 Because of the deeply-rooted survival instinct, people have used locally available drugs of natural origin for centuries. Several countries have identified useful drugs of natural origin, mainly medicinal plants, and considerable efforts have been made for their standardization. The use of these drugs in traditional medicine has been described in many countries. Chemical, biological and clinical research to identify and isolate active substances which could be applied in modern medicine have been carried out extensively and certain important results have been obtained.

5.11.2 National policy on traditional medicine is a matter of concern in many countries. However, countries having adequate modern health care resources and trained health manpower may have different policies from those where resources and manpower are still insufficient. In the latter, the use of medicinal plants and other natural products available in the country might be very useful in organized health care. Traditional medicine is a cultural heritage of the people and generally has high "consumer approval". A sudden change from traditional to modern medicine causes negative attitudes in the population towards the organized health care services. This leads to under-utilization of these services and to competition between them and traditional medicine.

5.11.3 Two main alternative approaches have been considered, namely:

- (a) integration of traditional with modern medicine; and
- (b) traditional medicine as parallel or complementary to modern medicine.

5.11.4 When integrating traditional medicine with modern medicine, the following problems are encountered:

- (a) Integration of traditional practitioners into health services in order to promote cooperation with health workers trained in modern health care. In this case, the role of each type of health worker should be clearly defined at each level of the health services.

Examples of this approach in action are education and training of the population in collection, cultivation and use of medicinal plants by traditional practitioners; identification, quality control, processing, preparation and dispensing of traditional drugs by traditional practitioners who act as pharmacists-dispensers.

(b) Education and training of health workers for both modern and traditional medicine. This approach has many advantages, especially in the primary health care setting because of its positive effects on consumer approval, thereby increasing the people's participation in community health care. By using this approach, a great deal of progress has been achieved in the primary health care of the population in several countries. In this case, however, the development of appropriate technology, as a supporting activity, is most important.

(c) Integration of traditional drugs with modern drugs. Health care began with the use of available natural substances by the population as a means of survival. Experience in the use of traditional drugs has been accumulated and utilized effectively by the people. There are many traditional drugs which could play an equal, or even more advantageous, role than chemical drugs. Symptomatic treatment is most frequently required in primary health care and, in many cases, the use of traditional drugs may be medically and economically justified.

5.11.5 When introducing traditional drugs into health care, two types of activity are required:

(a) to identify health conditions which can be treated by traditional drugs as effectively as, or even more effectively than, with modern drugs, taking into consideration the pathophysiological and psychosomatic aspects of the symptoms;

(b) to identify useful drugs, either medicinal plants or other natural substances, which can be used to produce traditional drugs.

5.11.6 After such identification, standardization of the drugs and their raw materials (medicinal plants) should be considered on the basis of pharmacognosy, quality, safety, etc. The appropriate technology for production should be developed in the following areas: collection, selection, cultivation, conservation (washing, drying, sterilization, insect decontamination, etc.), cutting, extraction and processing in the most suitable galenical form for distribution, storage and administration. It should be noted that many medicinal plants are unstable and special precautions for storage are required.

5.11.7 The use of medicinal plants should not be considered only for import substitution, but as an appropriate approach for developing countries to become self-reliant through development of appropriate health technology in accordance with their cultural heritage and natural resources.

5.11.8 If a country cannot integrate traditional medicine into health care, for political or social reasons, the government generally regulates independently the practice and the substances used in each system, i.e., issuing special requirements for education and training and giving a special license for each type of practitioner, along with established lists of approved modern and traditional drugs, using different evaluation systems.

5.11.9 Modern and traditional medicine should not compete with each other because both are valuable national health assets. The former is based on the development of science and technology and the latter is based on national cultural values accumulated by the people over a long period of time. Therefore, in spite of the different policies evolving in this area in various countries, common objectives and goals might be determined for the development of health of the people.

5.11.10 Furthermore, the traditional medical systems should be studied in the light of modern science and technology not only by individual countries but also in a collaborative research effort among both developed and developing countries. Through this effort, hidden treasures could more readily be discovered, exploited and developed to a higher degree in order to satisfy the real health needs of the people.

## 5.12 Self-medication

5.12.1 Although organized health care is rapidly extending, self-care, especially self-medication, still plays a fairly important role because of easy and quick access to treatment. Self-medication might be considered as a symbol of self-defence against disease when organized health care does not exist or is not available.

5.12.2 In developing countries, the health services are operating with limited resources and manpower which are often not constantly available, especially at the peripheral level. In this situation, home medicine and self-care can be given a greater role in community health services through:

- (a) much greater use within communities of the available health manpower for educational and training activities in health care, especially in the use of drugs;
- (b) improvement of the supply of pharmaceuticals and their utilization;
- (c) provision of valuable opportunities to the population in order to exchange information and to increase their participation in health activities;
- (d) incorporation of useful elements of traditional medicine and drugs into community health services for use in self-care, thereby enabling the community to utilize the most effective methods from both traditional and modern medicine.

5.12.3 Therefore, the objectives in promoting self-care in developing countries may be formulated in the following way: (a) increasing self-reliance in health care through community participation; (b) optimizing the utilization of health services; (c) increasing availability of health care to the population living in rural and remote areas; and (d) facilitating and increasing nation-wide availability of pharmaceutical supplies.



5.12.4 There are several constraints to be considered in implementing these self-medication activities, such as (a) the need to select appropriate drugs, especially safe drugs under various conditions of use; (b) commercial pressures for the introduction of proprietary name specialities which are usually more expensive; (c) the fact that communities which particularly rely on self-care often have no distribution facilities and very limited resources for purchasing drugs; (d) possible competition between the health workers in the organized health care systems and those helping the community in self-care on a voluntary basis; (e) the need for coordination of demand and supply, and hence for training activities and increased availability of supplies; (f) the fact that drugs for self-care are generally paid for by the consumer whose purchasing power is restricted by low income; (g) continued importation of most drugs and raw materials owing to limited technological resources and market.

5.12.5 Considering the above objectives and constraints, the policy on self-medication is formulated according to the situation existing in the most underserved populations. The following approaches can be considered in this respect:

(a) Selection of the most appropriate drugs for safe self-care with standardized labelling and instructions for use.

(b) Provision of adequate information and education of the public on the safe and effective use of drugs for self-medication.

(c) Establishment of an adequate distribution system for the continuous supply of essential items, together with control and guidelines for commercial distribution. The training of storekeepers and transporters would also be required.

(d) Price control and surveillance by government authorities.

(e) Encouragement of community participation in the use and distribution of drugs for self-care through community health committees and interested individuals. There is perhaps a need for short training courses for those motivated people to gain some experience to enable them to assist, when formally-trained health workers are not available in the community. However, those persons should not be in competition with formally-trained health workers and should work on a voluntary basis and, if offered, should only accept rewards following local traditions. Those persons would play an important role in acting as a link between health workers and the population, particularly in providing useful health information.

5.12.6 It should be stressed, however, that the indiscriminate use of self-medication leads to misuse and abuse of certain drugs, e.g., antibiotics, analgesics and psychoactive drugs. Adequate safeguards are therefore needed when such drugs are made available for self-care.