REPORT OF THE
WHO EXPERT COMMITTEE
ON NATIONAL DRUG POLICIES

Geneva, 19-23 June 1995

Contribution to updating the WHO guidelines for developing national drug policies
Contents

Page

List of participants ........................................................................................................... 1

Part I: Work of the Expert Committee ........................................................................... 5

1. Introduction .................................................................................................................. 7
2. Background .................................................................................................................. 8
3. Deliberations .............................................................................................................. 12
4. Conclusions and recommendations ........................................................................... 13

Part II: Contribution to updating the WHO guidelines for developing national drug policies ............................................................. 15

1. Introduction .................................................................................................................. 17
   1.1 Why a drug policy?................................................................................................. 17
   1.2 National drug policy as part of health policy ..................................................... 18
   1.3 What is a national drug policy? ......................................................................... 18
   1.4 Importance of the essential drugs concept ....................................................... 19
   1.5 What does a national drug policy help to achieve?........................................... 19
   1.6 Components of a national drug policy ............................................................... 19
   1.7 Process of national drug policy development ................................................... 21

2. Components of a national drug policy .................................................................... 23
   2.1 Legislation, regulations and guidelines .............................................................. 23
   2.2 Selection of drugs ............................................................................................... 31
   2.3 Supply .................................................................................................................. 34
   2.4 Pharmaceutical quality assurance ..................................................................... 39
   2.5 Rational use of drugs ......................................................................................... 43
   2.6 Economic strategies for drugs ........................................................................... 51
   2.7 Monitoring and evaluation of national drug policies ....................................... 59
   2.8 Research .............................................................................................................. 60
   2.9 Human resources development ......................................................................... 61
   2.10 Technical cooperation among countries ......................................................... 64

3. Process for establishing and implementing a national drug policy ...................... 69
   3.1 Setting priorities ................................................................................................. 69
   3.2 Formulating a national drug policy ................................................................... 70
   3.3 Implementing a national drug policy .................................................................. 72
   3.4 Monitoring .......................................................................................................... 74
   3.5 Evaluation ............................................................................................................ 74
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Part I

Work of the Expert Committee
1. Introduction

The WHO Expert Committee on National Drug Policies met in Geneva from 19 to 23 June 1995. The meeting was opened on behalf of the Director-General by Dr F. S. Antezana, Assistant Director-General, who drew attention to the task of the Committee, which was to review and contribute to updating the current WHO Guidelines for developing national drug policies (1). These guidelines, published in 1988, had resulted from a request by the WHO Conference of Experts on the Rational Use of Drugs, held in Nairobi in November 1985, when WHO had been asked to convene a group of experts to prepare guidelines for establishing national drug policies. This request was repeated by the Thirty-ninth World Health Assembly in 1986 in resolution WHA39.27 on the rational use of drugs, which had endorsed WHO’s revised drug strategy.

As a consequence, a working group of experts met in Geneva in 1987 to draft guidelines for national drug policies. The guidelines were later reviewed by the WHO Executive Board’s Ad Hoc Committee on Drug Policies, which met in Geneva on 9 and 10 January 1988. The final publication incorporated amendments and changes made by the Ad Hoc Committee.

To assist the Expert Committee in its work, Dr Antezana recalled important milestones, and the evolutionary process of the Organization’s work in the area of national drug policy development. He considered it important for this Expert Committee on National Drug Policies to have the WHO history and experience before it as background information during its deliberations.
2. Background

In 1975, the Twenty-eighth World Health Assembly, in resolution WHA28.66, stated that it was "convinced of the necessity of developing drug policies linking drug research, production and distribution with the real health needs...". In the same resolution, the Director-General was requested "to develop means by which the Organization can be of greater direct assistance to Member States in:

(a) the implementation of national programmes in research, regulatory control, management and monitoring of drugs and, in so doing, also in the formulation of national drug policies;
(b) advising on the selection and procurement, at reasonable cost, of essential drugs of established quality corresponding to their national health needs;
(c) the education and training of scientific and technical manpower for research, production, evaluation, control and management of prophylactic and therapeutic substances".

Following that resolution, the first WHO meeting on drug policies was held in December 1976.

The need for agreement on a selected number of essential drugs was repeatedly affirmed by representatives to the World Health Assembly, who recognized that the people who really needed essential drugs could not get them, chiefly because of a lack of technical and managerial know-how in procurement and selection and the waste of scarce money on non-essential items. The essential drugs concept was born, the first model list was published in the report of the WHO Expert Committee on the Selection of Essential Drugs in 1977,\(^1\) and today this is considered one of the success stories of the Organization. About 130 countries now have an essential drugs list.

On the basis of experience and data collected from many visits to countries in 1976 and 1977, the first WHO meetings and seminars that discussed national drug policies were held in 1977 in the Western Pacific Region (WHO Regional Committee for the Western Pacific, Tokyo, September 1977) and in March 1978 in the South-East Asia Region (Regional Seminar, Sri Lanka). Many of the elements of national drug policy set out in the 1988 WHO guidelines were developed during this work, culminating in 1978 with the background document presented at the Technical Discussions held during the 1978 World Health Assembly under the title "National policies and practices in regard to medicinal products; and related international problems". It covered (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; and (b) technical and administrative components in policies and management for establishing a pharmaceutical supply system to meet health needs.

The Thirty-first World Health Assembly (1978), in resolution WHA31.32, urged Member States _inter alia_ to "collaborate in the exchange of information on drug policies and management through bilateral or multilateral programmes and WHO", and recognized "the importance of an adequate supply of essential drugs and vaccines to meet real health needs of the people, through the implementation of national programmes of health care".

In view of the importance of the need for access and equity in essential drugs, the WHO/UNICEF Conference on Primary Health Care held at Alma-Ata, USSR, in 1978 included "access to essential drugs" as one of the eight elements of primary health care.

The WHO Executive Board also established an Ad Hoc Committee on Drug Policies that same year, in January 1978, to follow closely the recommendations on and development of national drug policy formulation.

In 1979 the Director-General, after presenting a report to the Thirty-second World Health Assembly, was requested "to establish a special programme on essential drugs, including its administrative structure" (resolution WHA32.41). The actual starting date of the Action Programme on Essential Drugs was February 1981.

In 1982 the Executive Board's Ad Hoc Committee on Drug Policies, on behalf of the Executive Board, presented a report to the Thirty-fifth World Health Assembly (2) on the work of the Action Programme on Essential Drugs. One of the Programme's main lines of action over the years from 1982 has been the "Development of national drug policies as part of comprehensive health policies". The report states "The development of national drug policies by all Member States is a major objective of the Programme". It further states: "These policies should form part of broader health policies for attaining the goal of health for all by the year 2000 based on primary health care, and should be realizable within the limits of the resources mobilized for their implementation. National drug policies should therefore 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 Committee noted Dr F. S. Antezana's involvement in the preparation of WHO guidelines for the development of national drug policies in 1982, when the Action Programme on Essential Drugs had convened a meeting on this topic of which he had served as Secretary (3). The report and annexes from that meeting had become the basis for the 1988 Guidelines.

Also in 1982, Member States were urged by the Thirty-fifth World Health Assembly, in resolution WHA35.27, "to develop and implement drug policies and programmes". This was reiterated by the Thirty-seventh World Health Assembly in resolution WHA37.32 in 1984, when Member States were urged "to intensify their action to introduce and implement drug policies along the lines endorsed by the 1982 Health Assembly.

In 1984, the Thirty-seventh World Health Assembly adopted a resolution (WHA37.33) specifically on the rational use of drugs, in which the Director-General was requested to arrange a meeting of all interested parties.
The resulting Conference of Experts on the Rational Use of Drugs, held in Nairobi in 1985, was a further milestone (4). Subsequently, in 1986, resolution WHA39.27 was adopted by the Thirty-ninth World Health Assembly after a detailed report on the Conference had been presented by the Director-General (5) together with a report on WHO's revised drug strategy (6). This resolution urged all concerned parties to assume their responsibilities, urged all Member States in a position to do so to support developing countries technically and financially, and decided that WHO would assume its responsibilities as listed in the Director-General's summing-up of the Conference (5).

One of the main tasks requested of WHO when its revised drug strategy was endorsed was to convene a group of experts to prepare guidelines for establishing national drug policies. A working group of experts met in Geneva from 16 to 20 March 1987 to draft such guidelines. The guidelines were later reviewed by the WHO Executive Board Ad Hoc Committee at its meeting in Geneva on 9 and 10 January 1988. The WHO Guidelines for developing national drug policies were thus published in 1988 incorporating the amendments made by the Ad Hoc Committee.

These guidelines, which the Committee was now being asked to review and to contribute to their updating, had since been used by a large number of countries in formulating their own national drug policies. More than 60 countries are now in the process of developing or implementing such policies with the help of the WHO Action Programme on Essential Drugs and its partners.

Other important Health Assembly resolutions followed in 1988, 1990, 1992 and 1994, calling for cooperation in the exchange of experience and information concerning the formulation and implementation of national drug policies and essential drugs programmes, for an increased effort of political will, and for optimal use to be made of the momentum gained in implementing national drug policies and essential drugs programmes consistent with WHO's revised drug strategy.

The current guidelines on developing national drug policies have served countries very well, as demonstrated by the many national policies that have been formulated. WHO has actively participated in this development, adapting the guidelines to the needs of individual countries at national workshops, and at intercountry seminars such as those for all French-speaking and Portuguese-speaking countries in Africa, held between 1991 and 1993.

It was felt, however, that with the experience gained from using the 1988 guidelines, important technical elements, administrative procedures, issues and developments should be addressed and reassessed. In a changing world, and with the expansion of the private sector, areas such as rational drug use need even more attention, as do public education in drugs; ethical criteria for medicinal drug promotion; generic drugs; and the importance of developing and securing human resources. Work on health economics and financing has to be expanded and enhanced, technical cooperation among countries can be increased, in a region or a subregion, and the harmonization of certain standards and procedures should also be discussed.

Finally, Dr Antezana observed that in the process of formulating (developing) and implementing national drug policies, countries should not lose sight of the overall need for equity and social justice, to make priority essential drugs available to all
who need them. This is particularly important in times when inadequate resources for drugs for HIV infection, AIDS, tuberculosis and sexually transmitted diseases are a great problem in most developing countries, or where resistance to antibiotics is a major public health problem.
3. Deliberations

The revised text of the guidelines that follows in Part II of this report reflects the Committee's deliberations during its review of major components that it felt should be considered in developing and implementing national drug policies. Because the development and implementation of national drug policies is a dynamic process, the Committee wishes to stress that these guidelines provide general principles and strategies that are in no way static and need to be adapted in the light of local needs, the type of economy, and other circumstances. The guidelines incorporate the concept of essential drugs and allow for economic, social and other differences among countries.

Throughout its work, the Committee underlined the importance of linking a national drug policy with the national health policy of which it should be part. Drugs and vaccines have the potential to confer enormous health benefits on a large number of people. Careful consideration was given to the opening remarks of the Assistant Director-General, Dr F. S. Antezana, and to the background information provided.

The Committee noted that, since 1988, when the previous guidelines had been issued, considerable changes had occurred in what is a complex and dynamic field. In some areas, such as regulation, selection, and quality assurance, progress has been continuous, with the regular production of WHO reports and publications. In other areas, such as drug use, economic strategies, and monitoring and evaluation, significant changes have occurred. The Committee wished to stress the importance of the components that are developed in the revised text. However, it recognized that a number of countries are implementing national drug policies in a variety of ways, emphasizing different components depending on country situations and needs.
4. Conclusions and recommendations

1. The Committee believes that the work of WHO in developing technical, managerial and administrative tools and in providing direct guidance and support to countries in national drug policy development and implementation has made, and will continue to make, a major contribution to public health through better access to essential drugs.

2. The Committee recommends to the Director-General that WHO continue to develop, expand, and adjust as necessary the technical, managerial and administrative tools needed for the formulation and implementation of national drug policies in accordance with the proposed guidelines. It further recommends that WHO continue to strengthen its support to countries in developing and implementing their national drug policies.

3. The Committee recognizes the major advances that have occurred in the rational use of drugs, economic strategies for pharmaceuticals, and monitoring and evaluation of national drug policies. The Committee therefore recommends to the Director-General that WHO undertake an inventory and analysis of these advances and identify appropriate approaches that could be effective in other countries.
Part II

Contribution to updating the WHO guidelines for developing national drug policies
1. Introduction

The prevention and treatment of diseases require an adequate health care delivery infrastructure and appropriate education, and high priority must be given to ensuring adequate sanitation, safe water supplies, and proper nutrition. Drugs play a crucial role in health care; they offer a simple, cost-effective answer to many health problems provided that they are available, accessible, affordable and properly used.

1.1 Why a drug policy?

In spite of the global increase in the production and consumption of pharmaceuticals, several countries continue to have serious problems in ensuring that drugs are available to the majority of the population; in many more countries, drugs are used in ways that are far from rational. The reasons for this are complex. They derive not only from financial and budgetary constraints, but also the characteristics of the market and the attitudes and behaviour of the government, prescribers, dispensers, consumers and the drug industry.

Consumers (i.e. the patients) have little or no part in the process of selecting prescribed drugs, and are often not fully aware of the activity, possible adverse effects, and appropriateness of the drugs prescribed for them. It is the prescribers who decide what the patient should get. If the prescribers have no access to independent drug information, they may then fail to choose for the patients what is best and most affordable.

Economic reforms, structural adjustment policies, trends toward liberalization, and reorganization of global trade and tariff agreements have further complicated the situation in several developing countries and made the objective of social equity still more remote. The pattern of drug demand is also changing in many countries as new diseases such as AIDS emerge, resistance to drugs (antibiotics, antimalarials, etc.) increases, and the epidemiological transition leads to a rise in consumption of drugs for chronic diseases.

To overcome all these problems, it is now widely accepted that each country should make positive efforts to achieve optimal availability and use of drugs for patients and consumers. In order for these efforts to be coordinated and to support one another, well designed overall policies need to be developed and implemented.

The experience of many countries has shown that all the different problems can best be resolved within a common framework. Every country should formulate and implement a comprehensive national drug policy to ensure that drugs of good quality, safety and efficacy are available at affordable prices to all those who need them, where and when they need them, and that they are rationally used. The policy developed will depend on the stage of economic development in each
country. At present, per capita expenditure on drugs varies from one or two dollars to over US$400 per head. Different issues will be emphasized in different countries within their national drug policy.

1.2 National drug policy as part of health policy

The drug policy should form part of a broader national health policy for attaining the goal of health for all based on primary health care, and should be realizable within the limits of the resources mobilized for implementation. The national drug policy should therefore relate to health systems based on primary health care, should include the concept of essential drugs, and whenever possible should emphasize preventive health care.

1.3 What is a national drug policy?

A national drug policy is both a commitment to a goal and a guide for action. It should be a written document containing objectives, priorities and the main strategies and approaches for attaining the objectives. Such an integrated approach, covering both the public and private sector, should help countries to make the best use of their limited resources in the health sector.

The ministry of health or its equivalent (analogous authority) is the principal agency and driving force in the formulation and implementation of a national drug policy in the context of the national health policy. Other concerned government ministries in fields such as planning, finance, industry, commerce, education, human resources development, internal security and foreign collaboration must also be involved, since their decisions affect several aspects of the pharmaceutical sector, for example, imports, trade barriers, tariffs, transfer pricing, intellectual property rights and drug trafficking. It is important, however, for the ministry of health to play a predominant role in all these areas to the extent that they affect the health of the people. The state has to guarantee the availability of equal access to effective, good-quality essential drugs at affordable prices for the entire population and to ensure drugs are properly used. This holds true regardless of the extent of government involvement in the pharmaceutical sector (i.e. whether the government is directly involved in procurement and distribution of drugs, whether it empowers a parastatal institution to carry out this function, or whether it acts mainly as a regulatory authority for a largely private pharmaceutical market).

However, the government is not the only entity involved in the national drug policy. The development and implementation of national drug policies calls for a partnership between the government, which acts in the public interest; those who take or consider taking medicines; those who prescribe medicines; those who dispense medicines; and those who make, market, distribute and sell them. Other partners therefore include universities and specialized institutes for research and training; institutions involved in the training of medical, dental, nursing and pharmacy personnel; schools for training middle-level and peripheral health workers; nongovernmental organizations such as professional associations, consumer groups, the pharmaceutical industry - preferably through national and international associations - and the legal profession.
1.4 Importance of the essential drugs concept

The essential drugs concept is basic to a national drug policy because it enables priorities to be set. The principle of the concept is that a limited number of drugs leads to a better supply of drugs, more rational prescribing and lower costs; quality assurance, procurement, storage, distribution and dispensing are all easier; training and drug information can be more focused; and prescribers gain more experience with fewer drugs and recognize adverse drug reactions better. Essential drugs are usually cheaper and the procurement of fewer items in larger quantities results in more price competition and economies of scale.

Essential drugs lists have now been adopted in both developed and developing countries and there is substantial evidence that this has contributed to a considerable saving in drug costs. Essential drugs lists have been adopted not only in the public sector, but have even been extended to the private sector in some developing countries, particularly where there is an acute shortage of foreign exchange.

1.5 What does a national drug policy help to achieve?

The goals and the objectives of a national drug policy will depend upon the country situation and the priorities set by the government. In the broadest sense it should make essential drugs available and affordable to all those who need them, ensure the safety, efficacy and quality of drugs available in the country, and promote their rational use by both prescribers and consumers. The policy must also take into account such areas as production, technology transfer, international collaboration, intellectual property rights, the role of the pharmacist in health care delivery, technical cooperation among countries and traditional medicines. In addition, the policy should be concerned with efficiency, equity and sustainability.

1.6 Components of a national drug policy

A number of components are widely recognized as being the most important to ensure that essential drugs are available at all times to those who need them and that drugs are used rationally. These form the basic framework of any national drug policy. They include:

Legislation, regulations and guidelines

The formulation of a drug policy should be followed immediately by the enactment of appropriate legislation and the introduction of regulations to provide a legal basis and make the policy enforceable. Legislation and regulation constitute important elements in any drug policy.
Selection of drugs

Selection of drugs is intended to extend the accessibility and rational use of drugs that meet the health needs of the population and at the same time can respond to the health needs of the individual.

Supply

A national drug policy should have as a main objective the availability of effective, good-quality drugs at a reasonable price. This implies that policies on production, procurement, storage and distribution must be established, with good coordination between the four areas.

Pharmaceutical quality assurance

A key element of the national drug policy is to ensure that drugs available in the country are safe, efficacious and of good quality.

Rational drug use

The goals of a national drug policy can only be achieved if medicines are used in an appropriate and safe way and only when needed.

Economic strategies for drugs

Efficiency and equity in the provision of drugs can be greatly enhanced by following appropriate economic strategies.

Monitoring and evaluation of national drug policies

When a country sets its objectives for a national drug policy, a process for monitoring and evaluation should also be put in place, so that progress in achieving the policy’s objectives can be assessed. This provides the basis for any adjustment to the policy as it evolves.

Research

Research is an important feature of national strategies for improving health. In the drug field, two types of research are important: operational research, and drug research and development. Both should be well integrated in the NDP.

Human resources development

Sufficient numbers of staff, with appropriate technical and professional capabilities, are required to implement a national drug policy consistently.

Technical cooperation among countries

Technical cooperation among countries is valuable in strengthening national and regional policies and contributing to the harmonization of legislation, regulations and guidelines on pharmaceuticals.
1.7 Process of national drug policy development

The process for formulating a national drug policy is a complex one; it requires dialogues with the different interests involved and a logical approach in identifying the substance of an appropriate policy. During the development of a drug policy, some elements considered may not be feasible, and choices need to be made at each level as to which are the most appropriate strategies and the most important activities for attaining the objectives. The range of strategies and activities that can be successfully implemented in a particular country is closely dependent on the pharmaceutical situation and the socioeconomic level of that country. In most instances the process will include the following stages:

- organize the policy process
- identify and analyse problems
- set goals and objectives
- draft the policy
- circulate and revise the policy
- obtain formal endorsement for the policy
- launch the policy.

Policy implementation is as important as formulation and should be carefully organized. There is no best way to implement a national drug policy, but consensus building, a committed and proactive government, and a flexible approach are keys to success.
2. Components of a national drug policy

The list of subjects with which a national drug policy can and often must deal is long. The components listed below are generally recognized as those that are the most important to ensure that only effective, safe, and good-quality drugs are authorized for marketing and to provide the basis for essential drugs to be available to the whole population and drugs to be used rationally.

2.1 Legislation, regulations and guidelines

Development

Legislation and regulation constitute important elements in any drug policy. The legal framework must take into account not only policy objectives but also the administrative, social and health infrastructure, the available human resources, and other resources. Legislation defines the organizations that are authorized to issue and implement regulations. This may vary from country to country. However, for practical reasons it is advisable to empower drug regulatory authorities to issue regulations to implement the laws. The formulation of a drug policy should be followed immediately by enactment of appropriate legislation and introduction of regulations to provide a legal basis and make the policy enforceable. Guidelines are often developed to facilitate/explain further the requirements of the law and regulations.

Within the context of the national drug policy and the other policy measures, strategies and programmes of action envisaged by the government, it is first necessary to identify the matters to be covered by the legislation. The objectives of the legislation must be clearly defined in relation to the available resources and existing infrastructure, as well as to future needs.

A law serves the primary function of distinguishing between what is permissible and what is not. A drug act, for instance, may stipulate who can import or manufacture drugs, who can sell certain categories of drugs, and which categories of drugs may be sold without prescription. Various authorities are needed to carry out a drug policy; their powers, duties and responsibilities should be clearly defined in the legislation.

Drug legislation and regulation should cover both the public and the private sector and must address the rights and responsibilities of the different parties concerned with drugs and pharmaceutical products, including medical practitioners, pharmacists, consumers, importers, manufacturers and distributors. These parties play different roles in ensuring that the needs of consumers are met. Legislation must establish the qualifications required for those entitled to handle drugs or it must state who has the authority to do so.
Matters concerning the qualification of health and other professionals, and prescribing and dispensing issues, are often decentralized to other entities and not detailed in the main drug legislation.

Legislation plays an important role in ensuring that pharmaceutical products are of good quality, safety and efficacy. It must also regulate their availability and distribution.

Legislation must also specify the sanctions that will apply in the event of failure to conform with any provisions of an act. Sanctions must be enforced if the policy is to function effectively.

Several legislative models and structures have been devised for the regulation of drugs. The circumstances of the country will determine the model of structure selected, but the basic elements listed below represent the minimum framework.

The basic elements are as follows:

- General provisions: title, purposes, extent, application and definitions.

- Specific provisions: control of the import, export and manufacture, distribution, supply, storage and sale of drugs, including authority for inspection.

- Other provisions: authority for the regulation of labelling, prescribing information and advertising, drug registration, scheduling of substances,\(^2\) and imposition of fees; the control of clinical trials and requirements for the protection of human subjects; monitoring of adverse reactions; and regulation of narcotic and psychoactive drugs under international control, if applicable.

- Prohibitions, offences, penalties, legal procedures and mechanisms for appeals against decisions.

- Assignment of powers to make rules and regulations.

- Repeals of existing laws in conflict with the act and transitional provisions.

- Exemptions from the provisions of the law (for emergency situations, rare diseases, donations, etc.).

These elements are sufficiently comprehensive and varied in scope to meet most of the objectives of a national drug policy. Some countries may not need all of them in the initial stages of implementation of the policy.

Some countries may decide to expand the basic model and include other elements such as:

- price controls
- generic prescribing

\(^2\) Legal category of a substance, e.g. narcotic or other controlled drug, prescription only, non-prescription.
- generic substitution
- drug reimbursement
- protection of intellectual property (patents and trademarks).

Similarly, other elements that are considered appropriate could be included in more comprehensive models. The guiding principle in selecting elements is that the country should have the administrative capability and the resources to enforce the legal provisions enacted.

Implementation

A law with modest aims and objectives that is properly implemented is preferable to a more comprehensive model that cannot be applied and remains a good law only on paper.

After a law has been enacted, the appropriate authority should draw up the regulations governing the standards and procedures for carrying out its provisions. These regulations are an essential part of the legislative process; they are also necessary to allow swift action in administrative matters. The regulations must be within the framework of the primary legislation, and the power to enact such regulations - which are delegated legislative actions - must be expressly conferred in the pharmaceutical law.

When new drug legislation is drafted, a plan for implementation should be formulated. Since implementation will depend on the resources available, a stepwise approach may often be necessary. Appropriate timing is important. Not everything can be done at the same time; for example, for countries establishing a drug registration system, intervals between the different phases may be a good solution.

Whatever model is chosen, a drug law depends on several inputs and resources for its implementation: personnel, physical requirements/infrastructure, and technical and financial requirements. Most important, however, is the existence of political will and commitment. If political commitment is lacking, implementation will fail.

Drug regulatory authority

In any branch of the health sector there has to be a central point from which the more important administrative and operational activities are directed. In the area of drug legislation different countries have provided for a variety of authorities and mechanisms to give effect to the legislation. How to resolve this question is a matter for national authorities to decide. There is no standard model to suit all situations.

A drug regulatory authority will involve or include any or all of the following:

- A central agency or department responsible for drug evaluation, drug registration, and review and renewal of registration. Other responsibilities include control of manufacturing standards and practice, import, export, distribution, labelling, product information, promotion and advertising.
- Inspectorate services responsible for inspection of premises for manufacturing, storage, distribution and dispensing and for sampling at ports of entry.
• Quality control laboratories.

As concerns inspection and quality control, these tasks may be shared by the central and local government authorities, particularly in countries with federal structures.

In addition, the regulatory authority may appoint advisory bodies and expert technical committees to facilitate implementation of the legislation, with due regard to conflict of interest. Attention should be given to the transparency of the meetings and the recommendations or decisions made.

**Drug registration and licensing**

The process for approval of pharmaceutical products, known as "registration", "licensing" or "marketing authorizations" in some countries, involves a series of different but complementary procedures. In a comprehensive drug registration system, adequate data on pharmaceutical, pharmacological, toxicological, therapeutic and clinical investigations must be available, and the personnel must have the ability to analyse the data. Documentation on these subjects is now very extensive because of advances in medical and pharmaceutical knowledge and stricter requirements for safety and efficacy. Countries that do not have the professional staff to evaluate and handle such documentation fully may wish to seek technical advice from WHO and/or from other countries with more advanced regulatory agencies. They may also wish to take account of regulatory decisions made in other countries. The authorities in some countries publish summary assessments of specific drugs and/or brief explanations of their reasons for accepting or rejecting applications for pharmaceutical product approval.

A full registration or licensing procedure involves detailed evaluation of data submitted in support of the safety, efficacy, and quality of a pharmaceutical product before a marketing authorization is granted. The process also determines the indications for the product's use and whether its sale requires a prescription. The procedure includes both assessment and post-marketing surveillance and reassessment of the product. Generic drug registration is usually handled through an abbreviated application procedure. Some countries have initiated a "fast-track" registration procedure for certain drugs or classes of drugs as a component of their national drug policies.

Introduction of a full procedure may not be possible at an early stage, in which case a simplified procedure can be applied - either a notification procedure or an authorization procedure.

A notification procedure involves obtaining information on all pharmaceutical products offered for sale and/or available in the country. The amount of information requested in a notification may vary. It may initially be restricted to the names of the pharmaceutical product and of the manufacturer. It may then be expanded to require notification of the nonproprietary names for active substances, the composition (including inactive ingredients), the pharmacological action, and the therapeutic classification.

In an authorization procedure, regulatory authorities review documentation on registration decisions by other regulatory authorities.
If drugs are not covered by any of these procedures, and exceptions have not been granted for them, they should be considered illegal and enforcement action should be taken.

**Approval of pharmaceutical products**

Efficacy, safety, and good quality are prerequisites for the approval for sale of a pharmaceutical product. Drugs should be approved only if adequate and scientifically based data on efficacy and safety are available from clinical studies and evidence of performance in investigational use in a variety of medical settings has been obtained and evaluated. Clinical trials should ordinarily not be required for registration if adequate data are available from studies in other countries. However, some countries may need to conduct one or more small clinical trials because of differences in health care systems, medical practice concerns, population differences or the need to conduct bioequivalence studies in certain cases.

Information for the health professional, and where appropriate - e.g. for all or for certain prescriptions and all non-prescription drugs - information for the consumer, should be approved by the authority.

In recent years, there has been a movement towards harmonization of international standards and guidelines for the evaluation of new pharmaceutical products. The sharing of information on drug evaluation among countries is also increasing, WHO taking a leadership role.

For example, a summary of product characteristics is approved by some national regulatory authorities as part of the authorization process for each product. Other drug regulatory authorities produce a similar document, or components of such a document, which becomes available after approval of the drug product. While these documents may not satisfy all the information needs of an authority in another country, they can make a contribution to the approval process. A decision not to approve a drug product may also be available. In addition, the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce provides for the exchange of officially approved, product-specific prescribing information on the safety and efficacy of finished products between governments.

Regulatory authorities are encouraged to collaborate with each other so that the efficacy, safety, and quality of pharmaceutical products can be efficiently evaluated during the approval process.

**Post-marketing surveillance**

Post-marketing surveillance is a mechanism for the systematic collection and analysis of data on how drug products are being used in the market and to what effect. Observations are normally made on safety, efficacy, and quality. In addition, drug prices, cost, drug use (rational or irrational), medical need, antibiotic and anti-parasite resistance, medication errors, drug product quality defects, habit-forming and narcotic drug abuse, and traditional medicines are usually monitored.

The drug regulatory authority has the task of ensuring that all drug products on the market are duly registered, comply with the conditions stipulated during registration, are relabelled for new warnings, adverse reactions and
contraindications, and are removed from the market should circumstances so warrant.

**Monitoring of adverse drug reactions**

It is recognized that clinical trials, though adequate to justify registration of a drug for general use, may fail to reveal uncommon adverse reactions. Hence there is a need to establish national systems for pharmacovigilance in order to collect and evaluate information on pharmaceutical products, with particular reference to adverse reactions (7, 9).

Pharmacovigilance data are only meaningful if they serve to support the drug regulatory authority in taking action. Hence, in countries without a regulatory authority that functions satisfactorily, establishing a national pharmacovigilance system may not be a priority. For this reason, and in particular in emergency situations when serious adverse reactions occur, such information needs to be communicated to participating and non-participating countries through the WHO Collaborating Centre on Adverse Drug Reaction Monitoring in Uppsala (Sweden). If necessary, the information can also be sent out through a Drug Alert message as part of WHO's information exchange programme (9).

If serious adverse reactions lead to withdrawal or severe restriction of a drug in one country the precise reasons and circumstances must be made known to others. Since conditions may vary between countries, regulatory action may be justified in one country and not in another.

Each country should alert its health personnel to the need to report adverse reactions promptly to the regulatory authority. Proper reporting forms should be available and electronic or other means of reporting should be specified.

The principal objectives of monitoring are to detect any adverse reactions, to minimize the time taken for their recognition, and to determine their overall importance in relation to the rational use of the pharmaceutical product.

The main activities of national centres for the monitoring of adverse drug reactions should include:

- The collection of data from such sources as voluntary reports from practising doctors, comprehensive monitoring in hospitals, the pharmaceutical industry, and data on defined populations.
- Verification of data.
- The analysis of data. The quality of the results of the analysis will depend on the quality of the system for data storage and analysis.
- The support and promotion of comprehensive specialized monitoring centres and systems which can provide additional data, such as demographic data, and which may be especially useful for the investigation of drug safety problems.
- Provision of feedback to individuals reporting data.
- Making validated data on adverse reactions available to non-participating countries, health professionals and, if requested, pharmaceutical companies.
- Monitoring the impact of their warnings on prescribing patterns and drug use.

Confidentiality of individual patient data and information on reporting persons should be guaranteed.
The limitations of systems based purely on voluntary/spontaneous reporting should be recognized. This is especially a problem for tropical disease drugs that are used primarily in countries with limited human and financial resources. In some countries prospective cohort studies have been set up, based on pharmaco-epidemiological methods.

**Monitored release**
The data available on certain drugs intended for the treatment of specific diseases or appearing to have special advantages for some patients may not be sufficient to permit their release for general use. In such circumstances it may be desirable to release the drugs on a restricted basis, e.g. for use only in hospitals with special arrangements for monitoring patients.

**Regulations on the distribution and prescription of drugs**
Strategies for the distribution and marketing of drugs constitute an integral part of any national drug policy. Drugs must reach the consumers who need them and do so at the right time. A drug act cannot by itself ensure that drugs reach those in need of them, but it can help in establishing efficient channels of distribution. Drugs constitute a special kind of consumer goods, which must not be indiscriminately distributed.

The regulations should stipulate who is entitled to distribute, prescribe and dispense drugs and indicate that drugs can be placed in different categories.

Whether a drug should be obtainable only on prescription or should be available for self-medication has to be decided after careful evaluation. Consideration of the prescription status of a product should be linked to the registration procedure. Drugs will normally be classified in prescription and non-prescription categories. Other categories may be stipulated by the regulatory authority, for example narcotics and psychotropic substances.

In general, only registered medical practitioners, dentists and veterinarians should be authorized to prescribe drugs in the performance of their professional work. However, limited prescribing authority may be granted to nurses and other health personnel who have received adequate education and training.

A licence should be required in order to establish a pharmacy. In the same way as manufacturers and wholesalers, a pharmacy must have adequate premises and be operated in accordance with professional standards. It should be managed by a registered pharmacist. In some countries the licensing of pharmacies is used to regulate the number of new pharmacies and to achieve a more even distribution. Where desirable, such measures may be considered.

Prescription drugs should be dispensed to patients only by pharmacists or through approved health institutions. However, dispensing authority may also be granted to pharmacy technicians and other health personnel who have received adequate training. Physicians sometimes need to dispense medicines to their patients as part of their practice. In these circumstances they should be required to maintain adequate controls and records.
Specific legal issues

Patents
Protection of intellectual property must be considered in developing a national drug policy. The issues are complex and involve commercial and industrial activities. The appropriate agencies within the government should therefore work jointly to develop an overall policy for the country in relation to national priorities on this issue.

Policies on brand and generic names
Since the 1950s, WHO has been responsible for assigning international nonproprietary names (INNs) to pharmaceutical substances. These are generic names used for the easy identification of drugs.

Companies involved in research and development generally market their products under brand names (trade marks). In many countries, new pharmaceutical products are protected by a patent. When the patent expires other manufacturers may enter the market with the same drug. The original company in most cases continues to sell the product, using the brand name originally adopted. New competitors may also give the product their own brand name or may simply use the generic name.

Pharmaceutical products may be offered for sale either under a specific brand name (trade mark) or under the generic name. Multiple-source products may be put on the market either under a given brand name (branded generics) or under the INN or generic name alone (commodity generics). A generic name is not the exclusive property of any individual person or corporate body. Brand names, on the other hand, are a form of commercial property. The question of brand names therefore has to be considered in the light of the country's general policy regarding commercial property, a policy that will involve other commercial and industrial products in addition to pharmaceuticals. For this reason, when national drug policy in relation to brand names is being decided, including such questions as permission to include the brand name on the label or what prominence it should have, consultation between the departments of health, trade, and industry and a review of the experience of other countries that have used alternative systems are advisable. Measures to regulate the use of brand names should take into account long-term national and social goals, including the need to encourage investment and research.

Prescribers may be allowed to prescribe by brand name or by generic name, specifying the manufacturer if two or more products are available for the same indications. Different countries, and different health institutions within them, use a variety of means to encourage prescribing and dispensing by generic names. A pharmaceutical product sold under its generic name is usually cheaper than its identical or equivalent branded product; prescription of generics can therefore result in significant monetary savings. In the purchase of drugs, however, whether or not potential savings are foreseen, the ability of the supplier to ensure continuous supplies of good quality is paramount. This may be especially important in countries where the regulatory agency is unable to ensure the quality of pharmaceutical products; there the cost of providing such assurance has to be weighed against the savings anticipated in the purchase of the least expensive products.
Generic substitution is practised in some health care systems where the dispensing of less expensive generic products may be optional or required. In such a case a constantly updated formulary of interchangeable generic drugs is needed.

National drug policies need to take into account international treaties and conventions to which the country is already a party, e.g. the Convention on Psychotropic Substances and the Single Convention on Narcotic Drugs as well as arrangements under the General Agreement on Tariffs and Trade/World Trade Organization.

2.2 Selection of drugs

The selection of drugs to meet the health needs of the population is an important part of a national drug policy. It provides a rational basis not only for drug procurement at the national level but also for establishing and meeting drug requirements at different levels within the health care system.

Principles of drug selection

The selection of drugs is intended to rationalize the use of drugs that satisfy the health needs of the population and that at the same time can respond to the health needs of the individual. Universal principles include drug efficacy, safety and quality. In addition, the principles of medical need and relative cost-effectiveness are influencing factors. The selection process and selection criteria should be applicable to the choice of drug substances as well as to the pharmaceutical products containing these substances.

Selection process

A standing committee should be appointed to give technical advice. The committee should include individuals competent in the fields of medicine, nursing, pharmacology, pharmacy, public health, and consumer affairs.

Because the success of any national drug policy depends on its general acceptance, transparent mechanisms should be established for consultation with interested parties, including representatives of professional bodies, pharmaceutical manufacturers, and consumer organizations. While such formal and informal consultation with representative interests is needed to ensure that the selection of drugs reflects broad policy objectives, the process of drug selection by the committee members should be carried out independently. In this process, only international nonproprietary names should be used.

Crucial stages in the selection process are to:

- identify the health problems
- define standard treatment guidelines
- identify drugs needed.

The appropriate health authorities should decide on both the specified level of care and the qualifications of health workers that are required for prescribing one or more drugs in particular therapeutic categories. Consideration should also be given to the competence of such personnel to make a correct diagnosis. While in
some cases health staff with more advanced training may be needed to diagnose and initiate treatment, it should be recognized that personnel with less training may be able to supervise maintenance therapy.

An essential drugs list should be updated at least every second year and more often if necessary. Revision is likely to be needed because of advances in drug therapy and in order to meet needs in the light of clinical experience.

The application, implementation and impact of the resulting list should be monitored on a regular basis.

Selection criteria

The choice of drugs depends on many factors, such as the pattern of prevalent diseases; the treatment facilities; the training and experience of the available personnel; the financial resources; and pharmacogenetic, demographic, and environmental factors. The following criteria will enable a rational selection process.

i Drug selection should be based on evaluations of efficacy and safety obtained in controlled clinical trials and/or epidemiological studies; if necessary, reference may be made to other regulatory authorities that have already taken decisions based on clinical trials. Guidelines for such trials have been set forth as an annex to the report of a WHO Expert Committee (10).

ii Regulations should be formulated to ensure that the selected pharmaceutical products meet adequate quality control standards, including stability and, when necessary, bioequivalence. Suppliers should provide documentation of the drug's compliance with the requested specifications. This is especially important where national resources for this type of control are not available.

iii Cost represents a major criterion in selection. In comparing the costs of different drugs the following elements should be taken into account:

(a) the cost of the treatment regimen rather than the cost of the dosage form;
(b) the cost of treatment in relation to the savings made by, for example, reducing the need for surgery or hospitalization;
(c) different rates of success of treatment achieved, as a result of variations in patient compliance;
(d) reduced loss or waste achieved by using more stable products.

iv When several drugs are available with the same indication, or when two or more drugs are therapeutically equivalent, the aim should be to select the pharmaceutical products that provide the most favourable risk-benefit and cost-benefit ratio.

v Essential drugs should in principle be formulated as single compounds. Fixed-ratio combination products are acceptable only when the dosage of each ingredient meets the requirements of a defined population group and when the combination has a proven advantage over single
compounds administered separately in therapeutic effect, safety and
compliance.

vi New drugs should be introduced into an essential drugs list only if they
offer distinct advantages over drugs selected previously. If new
information on drugs already in the list shows that they no longer have a
favourable risk-benefit ratio, they should be deleted and replaced by safer
drugs. It should be remembered that, for certain conditions, non-
pharmacological forms of therapy or no therapy at all may be preferable.

vii When two or more drugs are similar, preference should be given to drug
products on the basis of established local experience in therapeutic use
and/or their production in reliable local facilities.

viii As a general rule, pharmaceutical dosage forms are selected on the basis
of their general utility and availability. In many instances, a choice of
preparations is provided, particularly in relation to solid dosage forms.
The selection should also be based on a consideration of
pharmacokinetics, bioavailability, stability under ambient climatic
conditions, and established local preference.

ix The increasing prevalence of strains of common pathogenic bacteria and
parasites resistant to widely available, relatively cheap anti-infectives
included in the WHO model list is, in many cases dangerously eroding
these products' effectiveness. Knowledge of prevailing sensitivity
patterns is vital to the proper selection and use of such drugs, and to the
development of appropriate prescribing policies.

Applications of drug selection

National drug policies should be explicit with respect to the application and
authority of essential drugs lists, national formularies, or other forms of selective
drug lists. The preceding selection criteria are universally applicable, and may
be applied in different settings for different objectives.

National essential drugs lists and national drug formularies should serve as the
basis for all formal education and in-service training of health professionals, for
the preparation of formulary and therapeutic manuals, and for health education
of the public about drug use. Essential drugs lists should serve as the primary or
exclusive basis for public-sector drug procurement and distribution. They
should also serve as the basis for drug donations (see section 2.3) and for supply,
training and monitoring.

Selective drug lists may be developed and used by social security organizations
and other health insurance organizations for reimbursement purposes.

The concepts of drug selection can equally be applied to the selection of medical
supplies, reagents and equipment.

Traditional medicines

In many countries experience has been accumulated in the use of locally available
drugs of natural origin, mainly medicinal plants, and some of them have been used
effectively. Symptomatic treatment is frequently required in primary health care and in these cases the use of traditional drugs may often be medically and economically justified. Some countries may therefore wish to include traditional medicines in their national drug policy. When introducing traditional medicines into organized health care, countries should:

- identify the health conditions that can be treated by traditional medicines;
- develop appropriate methodology and technology for the identification, development and production of traditional medicines to enhance their medical, economic and sociocultural benefits and acceptance;
- undertake studies to evaluate the safety of the drugs;
- encourage patients, physicians, pharmacists and other health workers to notify adverse reactions, especially when herbal remedies are used in large amounts for prolonged periods.

One of the more difficult issues with traditional medicines is their nomenclature. They are usually known by a local name, which often varies from one country to another. While there are a few pharmacopoeias that include official names, there is no well recognized convention for naming these substances.

A committee including traditional healers and experts in phytotherapy, pharmacognosy, toxicology and other related fields should establish the criteria for selection of traditional medicines for health care systems. Use of the WHO guidelines for the assessment of herbal remedies is recommended (11).

2.3 Supply

A national drug policy should have as a main objective the availability of effective, good-quality drugs at a reasonable price. This implies that policies on production, procurement, storage and distribution must be established, with good coordination between the four areas.

Local production

There are three main types of pharmaceutical production:

- production of active substances and intermediates;
- production of finished dosage forms from excipients and active substances;
- packaging of finished products or repackaging of bulk finished products.

The production of active substances and intermediates should not be an objective in itself. It depends on the availability of natural resources or on a long tradition in the chemical and related fields. A study of the international market for pharmaceutical raw materials - including their costs - and of global needs should precede any initiative in this area. Information on the price of some raw materials is available from various sources, including WHO. However, price should be considered together with the quality offered/guaranteed.

The practicability of building up, step by step, a viable pharmaceutical production industry, with the aim of achieving self-reliance in pharmaceutical supplies, depends on many factors. These include: (a) population size and per capita
income; (b) the available technical human resources and supporting infrastructure; (c) the geographical and climatic conditions; (d) water and energy supplies; and (e) the distribution network.

Some countries consider that drug manufacturing plants may contribute to reducing foreign exchange needs, providing employment, and improving the balance of trade, and contribute to industrial development in general. However, the economic conditions for efficient production are frequently very stringent and sometimes the supply of drugs is better achieved through international trade.

The decision to develop local drug production is not based only on economic criteria. It can also be based on social, political and strategic factors such as to:

- create jobs
- provide drugs to national and international public health programmes aimed at disease control.
- reduce excessive dependence on imports.

There are often major limiting factors. In many cases, it is not possible to produce economically all the pharmaceutical products needed in one country. Ideally, therefore, cooperation between countries is desirable. Some countries may wish to consider participating in regional arrangements with neighbours so as to achieve economies of scale and greater cost-effectiveness. The decision as to whether essential drugs are to be produced by a government factory under the responsibility of the ministry of health or the ministry of industry or by private industry depends on local conditions and the sociopolitical structure of the country. When local production of drugs is to be established it is important to ensure that the products meet appropriate standards of quality.

When undertaking market analyses and other financial studies, particular attention must be paid to the prices of products with which locally produced drugs will compete. In cases where the prices of generic products in international trade will probably be lower than those of locally produced drugs, the advantages and drawbacks should be carefully analysed before investing in production. It is important that drugs sold under INNs should be among the drugs produced. Generic products will soon represent an increased share of the drug trade in the developed world; developing countries should therefore encourage this type of product through their national drug policy.

Developing countries interested in undertaking local production should also take into account the following considerations:

- Command of the appropriate technology is a critical factor, but managerial maturity and skills are just as important.
- The capacity of the local market (mainly in the private sector) to absorb local production should be carefully estimated. The public sector often operates on a limited budget.
- Exports to neighbouring or other countries can be achieved only if there is sufficient demand and if good-quality drugs can be supplied at favourable prices; exports should not be the prime objective, but an additional element to give the production project a stronger base.
• Local production should be aimed initially at the large-scale supply of essential
drugs under their generic names.

Some categories of drugs or drug products, such as ointments and solutions, may
be more suitable for local production in the initial phase. Materials for such
products are generally available locally.

Vaccines need special consideration. Before a decision is taken to produce
vaccines, such factors as the rapid progress of biotechnology and the availability
on the world market of vaccines of high quality and low price should be
considered.

Procurement

To ensure that the population has access to pharmaceuticals, procurement in both
the public and private sectors should be performed efficiently. In the public sector,
the system should be based on a systematic tendering procedure with
prequalification of suppliers. As pharmaceuticals represent an important part of
public purchasing and are among the commodities most needed by a country, it is
essential, particularly when economic resources are limited, for the government or
public agencies concerned to establish a system of procurement from multiple
sources of supply, domestic or international. Substantial public savings can accrue
from effective procurement. In the private sector, this mode of purchasing can be
used for the most important products in terms of sales.

Drug procurement should be adapted to the needs of the public and the private
sectors. The public sector should follow the national essential drugs list.

Procurement should include a quality assurance system covering registration,
quality control, control of imports, effective drug inspection and the application of
the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving
in International Commerce.

Market intelligence is of enormous benefit for drug procurement and strengthens
the country’s bargaining power. It can be obtained through continuous survey and
analysis of:

- supplier performance, including reliability;
- price trends, with early detection of speculation and other influences on the
  market;
- the reliability of quality assurance, e.g. through batch certificates and
  control;
- information on new drugs, especially their registration status in the country
  of origin and elsewhere;
- information on product interchangeability, as described in the guidelines
  on registration requirements to establish interchangeability adopted by the
  WHO Expert Committee on Specifications for Pharmaceutical Preparations
  (12).

Procurement organizations

In some developing countries in the public sector a procurement system, based on
worldwide tender, has been established as one of the activities of the ministry of
health. The system includes private and public facilities for storage, packing, repackaging, transport, quality control, and often production of some dosage forms, e.g. powders, ointments, solutions and elixirs. The administration of such a system requires the technical and financial expertise that is provided by professionals such as pharmacists and accounting and statistical staff. Usually the procurement agency obtains not only pharmaceutical products and vaccines but also other medical equipment and materials. However, this model has not always been successful because of lack of financial resources, foreign exchange, bureaucratic procedures, low staff motivation, and so on.

Other models are being implemented in some countries, for example autonomous or semi-autonomous supply agencies. These are established as parastatal bodies under the ministry of health or as independent organizations. The objective is to achieve the efficiency and flexibility associated with private management while maintaining a public health approach through some form of government control.

In the private sector, wholesalers undertake the procurement of drugs and their distribution. The number of wholesalers will vary; in most developed countries, it is tending to decrease.

Procurement process

In the public sector, the first step in the procurement process is to prepare estimates of the types and quantities of pharmaceutical products that will be required annually, biannually, or quarterly to satisfy the needs of the health services. Ideally, estimates of types and quantities should be based on up-to-date health information and should take into consideration the available financial resources. In many developing countries these requirements are difficult to meet in the initial phase owing to incomplete or unreliable information regarding disease patterns. In practice, therefore, the estimates are usually based on past drug use, and may be re-evaluated and revised through inventory control and utilization surveys. A practical manual describing methodologies for estimating drug requirements is available from WHO (13). These methodologies have proved helpful in achieving a more systematic approach to estimating drug requirements.

In order to keep the price of drugs low, products can be bought in bulk and repackaged in the country with standardized packing and labelling; the need for a clear distinction between different pharmaceutical products and their strengths should be kept in mind. Here special attention should be given to the clarification of product liability issues as well as to drug stability and pharmaceutical responsibility. The procurement agency will require specialized technical staff for packing, stock-keeping and quality control, and premises for storage and packing: this will increase the administrative costs.

The unit price of bulk drugs and/or pharmaceutical products can be considerably reduced by ordering large quantities. Whatever the status of the procurement agency, it is important to collect and aggregate drug needs at national level. Once the selection has been completed and the prices have been fixed, procurement can be done centrally or at lower levels. Accordingly, tenders should be requested annually, or at long intervals, for products that have a long shelf-life and stable international prices. Experience has shown that it can also be cost-effective for countries within the same region to procure a number of drugs jointly. The
procurement of patented products, or products produced by a few manufacturers, requires negotiation of price. Here market intelligence is of great importance.

Drugs are frequently donated by international organizations. These drugs should match the recipients' needs. Certain other guidelines should be followed. In particular, donors should provide drugs that are essential and have not expired; the expiry date should be verified by the donor. In addition, the national regulatory authority should be involved to ensure the quality of donated drugs. It is recommended that donors follow WHO's guidelines for drug donations (14).

Distribution and storage

The drug distribution policy is a key factor in the pharmaceutical supply system. It is necessary to devise and implement a system that leads to safe distribution of good-quality drugs at the lowest possible cost and that reaches the majority of the population, especially in remote areas of the country. Such a system is often best based on a combination of private and public sector initiative.

The existence of the distribution system in both the public and the private sector must be taken into account; however, each sector should be responsible for performing efficiently.

In the distribution system, the transportation of drugs should obey drug quality requirements, particularly maintenance of the cold chain and attention to maximum temperatures permitted for some pharmaceutical products. Distribution and storage by both public and private sectors should be regulated and monitored to ensure the quality of drugs at all levels of the distribution network. There is evidence that it is more efficient to use the private sector for certain drug transport and transit operations.

Wholesalers and retailers in the private sector should be taken into account when developing a national drug policy, particularly the distribution policy. In countries where the existing pharmaceutical distribution system is not sufficient to meet the population's needs, it may be useful to create intermediate and peripheral storage facilities managed by appropriately trained personnel.

This kind of distribution system allows easy geographical access to drugs needed. For this purpose, sufficient numbers of pharmacy technicians and auxiliaries will need to be trained. In addition, simple procedural manuals should be prepared and made available in all such storage facilities.

Because of the lack of product information and inadequate inventory control, drugs may remain unused in the storage facility. Information on drug procurement, needs and availability should be channelled to all those taking part in the distribution system.

The kit system has been used with success in several countries particularly in emergency situations. However, it is not suitable for long-term supply to health institutions.

While remuneration to cover the distribution costs for wholesalers and retailers is necessary to maintain distribution activities, its level should take into account the need for drugs to be affordable to the population.
The success of the national drug policy largely depends on the efficient distribution of drugs to patients. The provision of education, training and information for practitioners (prescribers and dispensers) also contributes to this success. Workshops and seminars on rational drug use are important in both public and private sectors.

2.4 Pharmaceutical quality assurance

Quality of drugs is of the utmost importance from the public health viewpoint. Establishment of quality is the first step in introducing new drugs (neither toxicological nor clinical studies have meaning without adequate, standardized quality and the guarantee that it may only vary from batch to batch and during the product's shelf-life within specified limits). Moreover, a test of a drug's quality is the first indicator, relatively easy to determine, that the product characteristics may have changed in a way that may also cause changes in its safety and efficacy.

Quality assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use. It is a system for organizing and monitoring the entire process, from the acquisition of a pharmaceutical substance to its conversion into a finished product and making it available to the consumer. Its purpose is to ensure that the user receives a product that meets all established specifications and standards throughout its shelf-life and at every stage of drug supply, and is safe, effective and of good quality. Pharmaceutical quality assurance therefore incorporates good manufacturing practices, similar requirements relevant to pharmacies (generally referred to as good pharmacy practices), and other factors, such as good laboratory practices and good clinical (research) practices, relevant to product design and development.

The acceptable quality for drug substances and products should be the same in every country. As far as possible, the same level of quality assurance should be applied to donated drugs.

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3 The term “quality” has been defined by the WHO Expert Committee on Specifications for Pharmaceutical Preparations (15) as follows:

The suitability of drugs for their intended use is determined by (a) their efficacy weighed against safety to health according to label claim or as promoted or publicized and (b) their conformity to specifications regarding identity, strength, purity, and other characteristics.

Although these two groups of factors may be considered separately, they are, to some degree, interdependent.

In order to ensure that all batches of a given drug are equally efficacious and safe, it is essential to establish adequate specifications for the drug and its dosage forms. The desired quality can then be achieved by strict adherence to these specifications. In fact, once their efficacy and safety have been established, the quality of drugs available in commerce is judged by identifying them and by determining their strength, purity, and other characteristics.
The aim of pharmaceutical quality assurance is both (a) to assure the quality of drugs directly and (b) to assure the quality of all professional pharmaceutical activities and services that may affect the quality of drugs.

Thus, quality assurance has a preventive character and has a broader scope than quality control that can simply identify mistakes that have already been made.

Coverage of pharmaceutical quality assurance systems

Pharmaceutical quality assurance systems should cover drug design and development, registration, procurement of drug substances, import and industrial manufacture of drug products, their compounding in pharmacies, and all types of distribution, including wholesaling and retailing.

Elements of a pharmaceutical quality assurance system

A quality assurance system has three basic facets: legal, regulatory and technical.

Legal base
The enabling legislation should provide the necessary authority for the development of specific regulations relating to quality assurance and assessment in all areas indicated above.

Regulatory elements
Regulatory elements should include the central drug control administration or drug regulatory authority (see section 2.1). Regulatory drug control should include the following activities:

- Registration of new drugs and its regulation (including terms of reference for registration, drug assessment and quality standards - see section 2.1).
- Licensing of drug manufacturers, wholesaler distributors, various types and levels of pharmacies and, in some instances, importers.
- Operation of the national drug quality control laboratory.
- Professional inspection of the drug supply chain, including other drug quality control laboratories.
- Recall procedures.

The system for regulatory drug control must prevent the procurement, marketing and use of substandard, counterfeit, false and spurious drugs (16, 17).

Technical and administrative elements
The technical elements of a quality assurance system should include quality specifications, basic tests, requirements for good manufacturing practices, and wholesale and retail pharmacy.

Good practices in the manufacture and quality control of drugs
Overall quality assurance in the manufacture of drugs, including proper organization of production and control activities, is essential to ensure that the consumer receives drugs of a high standard.4

4 At the Twenty-eighth World Health Assembly in 1975, the original text of “Good practices in the manufacture and quality control of drugs” was adopted. A revised text was approved by the WHO Expert Committee on Specifications for Pharmaceutical Products (19) under the new title “Good manufacturing practices for pharmaceutical products”. This new text contains three parts:
Although GMP principles are intended to govern drug manufacturing activities, some of their elements may be applied by drug distributors and wholesalers. Consequently, they form the basis of the inspections carried out by the drug regulatory authority (see section 2.1).

It is important to note that the GMP guidelines are directed more to organization, documentation and discipline in work than to the implementation of costly manufacturing technologies. The subject is by no means a theoretical one that only rich countries can afford. On the one hand, application of these international principles can prevent the possible harm to people caused by substandard medicines. On the other hand, once introduced, they may make production cheaper by reducing the number of substandard batches that must be re-manufactured or wasted.5

**WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce**

The Certification Scheme is of special potential value for countries with limited resources for regulatory drug control.6

The Scheme is non-mandatory and depends much on the good faith of the competent authorities in exporting countries. It is possible to join the Certification Scheme as an “importing” (certificate receiving) country exclusively, even if the country performs also some drug export activities. This is recommended for countries with limited resources for regulatory drug control. The WHO Certification Scheme is generally considered superior to “free sale certificates” for finished products (which do not cover data on government inspections to check compliance with good manufacturing practices, approved indications, etc.), and should replace them. The Scheme provides the importing drug regulatory authority with the expertise and independent information of the exporting country’s drug regulatory authority. However, it cannot take the place of licensing and registration. It is intended to strengthen such systems, not

- Quality management in the drug industry; philosophy and essential elements;
- Good practices in production and quality control;
- Supporting and supplementary guidelines (with sections on sterile pharmaceutical products and good manufacturing practices for active pharmaceutical ingredients).

5 The WHO Expert Committee on Specifications for Pharmaceutical Products has endorsed, as a supplement to the main GMP text, the guidelines on good manufacturing practices for biological products prepared jointly with the WHO Expert Committee on Biological Standardization (19). Supplementary guidelines on good manufacturing practices for herbal medicinal products as well as those on process validation were consulted.

6 Under the Certification Scheme, the competent drug regulatory authority of the exporting country must certify whether or not the drug is registered and permitted to be sold in that country. If it is, it must also submit the date and number of registration. If it is not, the reasons must be stated. The competent drug regulatory authority of the exporting country must also certify that the manufacturer’s facilities are inspected regularly (the date of the last inspection indicated) and that they comply with WHO standards of good practices in manufacture and quality control. Moreover, as a result of a current review, the therapeutic indications for which the product has been approved and/or the whole approved summary of product characteristics (data sheet) may also be provided together with the basis of approval. In 1998 and in 1992, the scope of the Certification Scheme was extended, in accordance with World Health Assembly resolution WHA41.18. Active ingredients were also included.
replace them. Moreover, maintenance of the national quality assurance system is still necessary, for the Scheme does not deal with transit and storage conditions once products have been released by the manufacturer.

**Stability of drug substances and products**

Stability studies should cover all pharmaceutical substances, not just a few critical ones such as biological products; the stability of all drug substances and products under extreme tropical conditions is equally important. The need for stability studies of products bought in bulk and repackaged in the country has already been emphasized above (see section 2.3).

**Structures of a pharmaceutical quality assurance system**

A pharmaceutical quality assurance system has two different but complementary components that may be used equally by regulatory bodies, manufacturers/importers, wholesalers, and other interested groups: inspection and laboratory quality control testing.

Inspection is intended to ensure that all the professional activities within the drug manufacturing and supply chain comply with the requirements of the licence as well as with professional regulations.

Quality control laboratories are responsible for checking, by appropriate testing, that drugs are of the required quality. Each drug regulatory authority should have access to at least one such laboratory, which will also play an important role in the registration process and the surveillance of marketed products. Regional laboratories answering local needs may also be established. At high levels of control, the establishment of quality control departments within drug manufacturers and wholesalers/distributors, working under the strict control of governmental inspectors and the national drug quality control laboratory, may be a prerequisite for the issue of the corresponding licences.

It should be noted that different structures and elements of quality assurance may have special emphasis in different areas. Thus:

- From the manufacturer's point of view, quality assurance may mean chiefly the application of good laboratory practices and good manufacturing practices (including quality assessment), extended also to product development and formulation.

- For drug regulatory authorities, it relates mainly to inspection to ascertain compliance with good laboratory, manufacturing and clinical practices, drug evaluation and post-marketing surveillance; it also covers the implementation and use of the WHO Certification Scheme for imported drugs.

- For distributors, it entails purchasing from reliable sources, inspection at the time of receipt, proper storage and dispensing, correct contract specification, targeted laboratory testing, reporting suspected quality defects to the national centre and so on.
2.5 Rational use of drugs

The goals of a national drug policy can only be achieved if medicines are used in an appropriate and safe way and only when needed. Therefore a policy on rational use of drugs is an extremely important part of a national drug policy. Its aim is to contribute to the health of the country's population by improving the use of medicines by health workers and consumers, and by encouraging the activities of government, industry and the media in support of rational drug use. Involvement of all sectors is particularly important as the actions of all (government, industry, health workers and consumers) at individual and group levels affect the way in which drugs are used. Governments can take a leadership role by adopting a clear policy on rational use of drugs that involves and encourages key groups to develop complementary policies and practice. For example, they may involve therapeutic committees responsible for the development of standard treatment guidelines; professional associations, which establish standards of professional practice and continuing education; academic institutions, which are responsible for basic training, research and practice support; industry; and consumer groups.

The factors influencing drug use are many and interrelated. Much still needs to be learnt, particularly about how people conceptualize illness and treatment and why they take certain actions. While research has produced interesting findings, very few of the insights gained have been used in the practical development of policies and programmes. No single approach is likely to work. Rather, a variety and combination of strategies tailored to the needs of the different groups in society and the different working environments of health workers will be needed.

Objective drug information

A medicinal product must be accompanied by appropriate information. The quality of information accompanying the drug is as important as the quality of the active substance. Information about drugs and drug promotion can greatly influence the way in which drugs are used. Monitoring and control of both these activities are essential parts of any national drug policy.

In a report to the Forty-seventh World Health Assembly in 1994 (20), the Director-General of WHO reiterated the importance of drug information and concluded that "a concerted effort is needed by ministries of health and of education, the academic world, consumer organizations and the pharmaceutical industry, WHO and other health and development agencies in their respective fields of competence to ensure improved drug information and use and related education and training".

Criteria that should apply to the development of objective information are that it should be: based on agreed standards; available, accessible and understandable to users; flexible and provided in a variety of forms; relevant to user needs; recognizing the multicultural nature of many societies; independent, unbiased and with no advertising; developed with user input; and pilot tested for usefulness and acceptability.

Drug information is the basis for the development of tools essential for rational prescribing and use such as formularies, standard treatment guidelines and consumer information. Without reliable information these cannot be developed.
Drug information can be provided through regulatory and other channels and should be targeted at specific groups with relevant messages.

**Drug information for health personnel**

**Regulatory information**
Information material in the form of drug information sheets and labels is provided by manufacturers as required by regulators. The content of this information is approved by the national regulatory authority. In its sixth report (21), the WHO Expert Committee on the Use of Essential Drugs gave a sample list of the information that should be included in the drug information sheet. The list is intended for adaptation, as appropriate, to each country’s needs.

**Other sources of information**
Comparative, independent, reliable and objective information is also needed for appropriate therapeutic decisions. This can be provided in the following ways:

- By establishing a drug information centre, which often requires government support to assure its autonomy.
- Through participation in the development of treatment guidelines and drug formularies, the formation of drug and therapeutic committees, involvement in teaching and clinical meetings, surveys of practice, and outreach services by staff from the drug information centre.
- By developing a national drug information bulletin or newsletter. This is particularly helpful in some countries since it can outline the justification for important decisions taken by the local regulatory agency and can offer objectively written articles focusing on drug use and appropriate prescribing practices.
- By disseminating independent scientific literature on the rational use of drugs and on therapeutic advances, as published by international organizations such as WHO, national regulatory authorities, and other scientific bodies, including material from peer-reviewed medical journals. WHO provides model prescribing information on the use of drugs for specific diseases. This is intended for adaptation to local needs.
- By the organization of training programmes, symposia, and lectures for the various groups of health personnel.
- By the development of treatment guidelines and educational material on the appropriate use of drugs by community health workers or paramedical personnel at the primary health care level.

**Drug information for consumers**
Information similar to prescriber information, but in language that is understandable for the non-health professional, should be provided to consumers. In many countries this is done through patient information sheets and drug labelling. These should be regulated to ensure accuracy. Other information may be provided in the form of brochures, through campaigns and, most importantly, through patient counselling. In populations with a low level of literacy, additional ways of presenting information can be used.

**Rational use of drugs by health personnel**

The therapeutic encounter between the patient and the prescriber/dispenser has a major impact on the quality of care. Even if drug supply and diagnostic services
are excellent, treatment may be inadequate. For the patient to receive correct treatment, the overall prescribing and dispensing environment must be supportive and this should be covered when policy is formulated. Strategies include the investigation and monitoring of drug use practices, leading to appropriate interventions to address identified problems.

Drug use practices by health personnel can be investigated relatively easily utilizing quantitative and qualitative techniques. When a significant problem is identified, an intervention should be developed to remedy the situation. The intervention should address the underlying cause of the problem, be targeted to those persons or facilities where the problem is most pronounced, and focus on a specific behaviour to be changed.

In the past, training alone was thought to be the solution to irrational drug use. However, in many situations, levels of knowledge have been found to be good while practice has been deficient. There are frequently other causes of inadequate performance.

Requirements for rational drug use

Adequate diagnosis
For a correct diagnosis to be made, the prescriber must have adequate knowledge and motivation, private examination facilities, and sufficient time to take a history, perform an examination, and explain to the patient the diagnosis and treatment.

Correct prescribing
To prescribe correctly, the prescriber must know which drug to prescribe for which diagnosis or complaint and when treatment without drugs is appropriate. Where nurses or basic health workers actually prescribe, they should be specifically trained to do this.

Appropriate dispensing
For correct dispensing to occur, the dispenser must be trained, have adequate time, have the necessary materials (containers, labels), and have a dispensary where it is possible to communicate with patients.

Patient adherence to treatment (compliance)
Patient adherence to treatment is dependent on understanding and acceptance of the treatment; this results from effective communication between prescriber, dispenser and patient.

Improvements are possible in all the areas listed above, provided that the underlying causes of any shortcomings have been clearly identified.

Measuring drug use
In any situation, measurement of present practices, followed by investigation of the underlying reasons for practices that represent problems, should precede the development of interventions. In 1993, WHO issued a manual entitled How to investigate drug use in health facilities (22).\(^7\) Other methods may utilize aggregated

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\(^7\) The indicators and methods set out in this manual have been used to measure drug use in over 20 countries and situations. The simple survey model proposed makes it possible to identify priority problem areas such as polypharmacy, excessive antibiotic or injection use, short consulting or dispensing times, and low patient knowledge.
information combining drug procurement and morbidity data to calculate consumption/morbidity ratios. The use of the Anatomical Therapeutic Classification (ATC) and Defined Daily Dose (DDD) systems may facilitate such studies (23). As computers are increasingly used to exchange drug utilization data, there is a need to standardize coding systems, for example for health problems, dosage forms, and the description of adverse drug reactions.

Once the priority problem has been identified, further investigations utilizing qualitative techniques such as observation, focus group discussions, in-depth interviews, questionnaires and simulated patients are required. The purpose of the further work is to understand why the problem exists and the underlying context.

Action to promote rational drug use
Any intervention should be focused on a specific problem behaviour and targeted at those individuals or facilities that exhibit the problem behaviour. In the development of interventions the participation of the target group in all phases of the activity is necessary to achieve the desired outcome.

Educational approaches
The education and training of health professionals and health workers form a major strategy to achieve rational drug use. The essential drugs concept and its practical application should be included in the curriculum of all health professionals and health workers.

Teaching medical students to prescribe rationally has a strong impact on the future. This applies also to situations where doctors are not the only prescribers, as their example has a strong influence on other health workers. However, it is now increasingly being recognized that traditional medical education concentrates too much on instilling a growing quantity of facts, rather than teaching the student techniques of problem-solving and making rational choices between drug treatment alternatives, which includes the skill to evaluate new drugs critically. This implies that the objectives of pharmacotherapy training need to be defined better, with more emphasis on the practical needs of the future prescriber. An undergraduate course in clinical pharmacology and therapeutics should teach the principles of rational evaluation of therapeutic alternatives before the students enter the wards.8

In addition, teaching hospitals have an ethical responsibility towards society to promote rational prescribing through the example of their teaching staff, which will then be followed by future generations of doctors. The best approach appears to be for clinical departments in teaching hospitals to develop departmental prescribing policies for common conditions, within the national list of essential drugs, through a process of consultation and consensus building. Such treatment guidelines can later be integrated into a hospital formulary and should be used, and enforced, as the basis for prescribing, teaching, examinations and medical audit.

8 A WHO student manual on good prescribing is now available (24). The methodology has been evaluated in seven countries.
Post-qualification training for prescribers is required in order to maintain and update knowledge and practice, and to correct identified deficiencies in practice. Whenever possible such training should occur on site and in small group or one-on-one interactions. Identifying and influencing opinion leaders is an effective way of changing practices within a professional group. Conferences and symposia offer further opportunities for education.

The prescriber is an important factor in patient education, a function that is often neglected. Guidelines already produced in one country can serve as models for other countries (25).

Managerial action
Options for managerial action to promote rational drug use can occur throughout the drug procurement cycle. The essential drugs list should be organized by levels appropriate to the expertise and training of staff working at that level. Estimates of procurement quantities should be based on morbidity rather than past consumption data. The allocation of drugs at each level of the health care system should be matched to training and supervision of health practitioners at that level.

Prescribing and dispensing can be improved managerially by audit and feedback (including the use of "exit" interviews of patients); structured drug order forms; standard diagnostic and treatment guidelines for different levels of health care; packaging in quantities required for a course of therapy; and mandatory consultations or justifications.

The option of audit and feedback has been shown to be among the most effective strategies progressively to improve prescribing.

Drug use databases are useful for ad hoc studies and to monitor the impact of policy changes.

Regulatory interventions
Regulatory interventions may be rapidly effective but can have unintended impacts. Thus they should be used with caution. Options that have been shown to be effective in some circumstances include: fixing priorities in the registration of drugs on the basis of medical need; restrictions on the level of use for both prescribing and distribution; dispensing controls, which can include limiting the quantities of drugs dispensed for some categories; and the use of convenient packaging, such as blister packs.

Combining actions
Whenever possible, interventions of different categories should be combined either simultaneously or sequentially. Such combinations have shown synergistic impact when evaluated.

Evaluation and selection of approaches
For policy-makers to determine which approaches have the greatest chance of success, careful evaluation is required. Such evaluations require good methodology, and a recognition that information is gained even from a negative outcome. At present the most successful interventions appear to be:

- Audit and feedback.
• Focused and targeted education, particularly when this includes face-to-face training in small groups, ideally involving an opinion leader.
• Developing essential drugs lists and standard treatment guidelines combined with focused training.
• Distribution of level-specific drugs combined with training and supervision.
• Structured drug order forms.

Rational use of drugs by consumers

Openness and effective communication are basic to the success of a national drug policy. Public participation in the design and implementation of such a policy will foster the effective use and control of drugs.

Public education in drug use

An important part of health education is public education in drug use. The overall aim of public education in drug use is to provide individuals and communities with information and to foster skills and confidence that will enable them to use medicines in an appropriate, safe, and judicious way.

Public education in the appropriate use of drugs is needed because without it people lack the skills and knowledge they require to make informed decisions about how to use drugs (and when not to use them) and to understand the role of drugs in health care. However, public education has often not been allocated the necessary human and financial resources, and is frequently treated as a marginal activity or one that should only be tackled when the other elements of drug policy have been dealt with. There is a need to increase the priority given to public education (26).

Irrational drug use has been well documented and includes problems of overuse, underuse and inappropriate use. Improving public understanding of medicines will not resolve all of these issues but, together with other activities to implement national drug policies, it will contribute to the development of solutions.

Principles to guide public education in rational drug use include the following:

• Drug use should be seen within the overall context of a society, community, family and individual. Public education on drugs should recognize and take into account cultural diversity and the influence of social factors such as poverty, disadvantages and power relations that can influence drug use.
• Public education should be part of national drug policies.
• Public education should encourage informed decision-making by individuals, families and communities on the use of drugs and non-drug solutions.
• Public education should be based on the best available scientific information on drugs, their efficacy and side-effects.
• Nongovernmental organizations, community groups, teachers, and consumer and professional organizations have an important role to play in public education programmes and should be involved in the planning and implementation of educational activities. It is helpful for consortia of such interested groups to meet regularly and plan joint activities.9

9 The National Council on Patient Information and Education, Washington DC, USA, is an example.
• Communications training of health care providers and reorientation of their attitudes to patients are necessary.

Education about drug use should begin at an early age; schools and the home have a key role to play in this respect. It is important that people understand some basic concepts relating to drug action and realize that drugs involve risks as well as benefits.

People should also receive information about the positive value of therapeutic medicines and how to choose when to self-medicate and when to seek medical advice.

People need to understand the correct use, benefits, and limitations of the drugs they take. They also need to understand that drugs can mask serious conditions.

*Constraints and facilitating factors*

The outcome of public education activities can be influenced by many factors. The nature and extent of these influences can vary from country to country according to the level of development and the health care infrastructure.

Factors that can act as constraints to public education include: a lack of policies on both drug use and public education; commercial interests; professional interests; weak infrastructures; lack of resources; and economic, social and cultural influences.

Factors that can facilitate public education include: a rise in levels of education and literacy in the country; increased awareness of the need for drug education; improvements in health infrastructures; and the expanding coverage of the world’s population by mass media.

Policy-makers need to consider both constraints and facilitating factors in programme development.

*Self-medication*

Self-medication is widely practised in both developed and developing countries. Medicines may be approved as being safe for self-medication by the national drug regulatory authority. Such medicines are normally used for the prevention or treatment of minor ailments or symptoms that do not justify medical consultation. In some chronic or recurring illnesses self-medication is possible after initial diagnosis and prescription, the doctor retaining an advisory role.

Responsible self-medication can:

- help to prevent and treat symptoms and ailments that do not require medical consultation;
- reduce the increasing pressure on medical services for the relief of minor ailments, especially when resources and human resources are limited;
- increase the availability of health care to populations living in rural or remote areas where access to medical advice may be difficult;
- enable patients to control their own chronic conditions.

Although the drugs authorized for self-medication will vary from one country to another - depending on the existing health care system, and social and economic
factors - the criteria for selection are common to all and should be based on
demonstrable efficacy and evidence of a wide margin of safety. The criteria and
process should be transparent (see section 2.1).

The drugs selected should be provided with labels and instructions that are
accurate, legible and clearly understandable by lay persons.

They should include complete information on the drug content, indications for use
and for stopping use, recommended dosages, warnings against unsafe use or
storage, and warnings against drug interactions.

Every attempt should be made to ensure the appropriate use of self-medication
and to guard against any unacceptable risks it may entail.

Promotional activities

In its resolution WHA41.17 (1988) endorsing WHO’s ethical criteria for medicinal
drug promotion (27), the Forty-first World Health Assembly urged Member States
“to take account of these ethical criteria in developing their own appropriate
measures to ensure that medicinal drug promotion supports the aim of improving
health care through the rational use of drugs”. This was reiterated by the Forty-
seventh World Health Assembly in resolution WHA47.16 (1994).

Drugs have a potential for harm as well as benefit that makes them different from
other commodities. Their promotion and sale require special controls. Hence
WHO’s ethical criteria aim to support and encourage the improvement of health
care through the rational use of medicinal drugs. The guiding principles are that
drug “promotion should be in keeping with national health policies and in
compliance with national regulations, as well as with voluntary standards where
they exist. All promotion-making claims concerning medicinal drugs should be
reliable, accurate, truthful, informative, balanced, up-to-date, capable of
substantiation and in good taste. They should not contain misleading or
unverifiable statements or omissions likely to induce medically unjustifiable drug
use or to give rise to undue risks. The word “safe” should only be used if properly
qualified. Comparison of products should be factual, fair and capable of
substantiation. Promotional material should not be designed so as to disguise its
real nature” (27).

An international meeting of all interested parties in 1993 (28) expressed concern
that the ethical criteria had not been widely disseminated and implemented. The
meeting affirmed that patients and prescribers have an inherent right to
information about medicinal drugs that is factual and supported by scientific
evidence. The meeting made specific recommendations on how the ethical criteria
could be furthered by relevant parties - national drug regulators, industry,
consumers, health professionals, international organizations, and professional and
general media - through education and communication, monitoring of
implementation and impact, international collaboration and adoption by countries.

National drug policies should include provisions for regulating promotional
activities. The WHO ethical criteria for medicinal drug promotion can serve as a
basis to develop measures to control drug promotion. Control can involve
regulation by authorities, self-regulation by industry through national and/or
international codes, and co-regulation. Screening or sampling of promotional
material by regulatory authorities should be considered. Consideration may also be given to controlling the type or amount of resources expended on promotion.

Drug regulatory authorities should develop mechanisms to monitor the promotion of drugs as part of their regulatory activities as well as in the monitoring of the national drug policy.

The problem of unrestricted availability of prescription drugs

The unrestricted availability in some countries of medicines that normally require medical supervision may result in their inappropriate use, delay in diagnosis, emergence of drug resistance, waste of resources, and toxic effects. This situation may have many causes. In such a context the need for public education becomes even greater. Training of drug sellers is a complementary approach that has shown promise in a few studies.\(^{10}\)

2.6 Economic strategies for drugs

Questions related to health economics have become more and more crucial in the formulation and implementation of national drug policies. Such policies have moved from the purely technical and pharmacological to the economic and social sphere. Each component of a national drug policy - including selection, supply, quality assurance, storage and distribution, and rational use - has economic effects.

Assuring stable and adequate financing for health care is becoming increasingly difficult as a result of the combined effects of economic pressures, the continued increase in population, and the increasing burden of disease. Health care resources are stretched by the demographic transition to older populations with more costly chronic diseases, the emergence of new diseases such as AIDS, and the resurgence of older diseases such as tuberculosis and malaria.

Macro-economic changes, such as structural adjustment policies, external debt problems or devaluations, have an important impact in the health field, and particularly on the financing of drugs. Furthermore, the new economic policies in the drug sector may have direct consequences, as yet not clear, on access, quality and rational use of drugs. The economic dimensions of national drug policies are therefore a question of concern, not only for ministries of health, but also for all other government departments.

The relationship between the public and the private sectors is an important consideration. Markets usually allocate resources efficiently, if competitive conditions prevail. But the pharmaceutical market, if left alone, may fail and monopolistic conditions may arise. Market features that may inhibit competition include inadequate information for health professionals and the public, the fact that consumers' choices are strongly influenced by those who prescribe and dispense drugs, the lack of proper incentives, exclusive rights such as patents and trade marks, promotion and advertising of particular products, and concentration of production among a small number of suppliers.

\(^{10}\) The WHO guide for improving diarrhoea treatment practices of pharmacists and licensed drug sellers (29) is an example of how drug sellers can be trained.
Government action is therefore needed:

- to establish a regulatory framework that ensures efficacy, safety and quality of drugs;
- to create the incentives required to guarantee competition for the benefit of consumers and the efficiency of the economy at large;
- to negotiate with suppliers when monopolistic conditions prevail;
- to provide access to essential drugs to the whole population, and particularly to finance the needs of the poor.

Markets do not necessarily achieve equity. The public sector has a responsibility to improve the distribution of health care and drugs among social groups. Taking into account the particular socioeconomic circumstances, every government should allocate a certain amount of resources to satisfy the essential drugs needs of the poor and other target groups.

Incentives for doctors, pharmacists and the general public are an essential tool to restore competition.

Economic strategies for drugs should be adapted to the particular needs of each country. Countries are diverse with respect to population, income levels, health expenditure and other relevant factors. National spending may vary from 2 to 400 US dollars per person per year.

Countries that are small, do not have the necessary infrastructure, or experience extreme economic hardship may find it difficult to achieve a sufficiently competitive pharmaceutical market. In such instances, public supply through competitive procurement and distribution through public health networks may be necessary. International cooperation, aid and technical assistance may be required.

**Organization of markets to foster competition**

With adequate institutions, information and incentives, national pharmaceutical markets can be organized to promote price competition.

**Rules to organize the pharmaceutical market**

First the basic rules have to be established. Some of the basic rules to organize pharmaceutical markets are peculiar to the sector: drug evaluation and licensing, quality assurance, and related issues. These rules have both technical and economic implications. Some rules are common to other sectors; for example, public purchasing regulations and laws on patents and trade marks. An appropriate functioning of these rules is necessary for the market to work.

Pharmaceutical firms and products must comply with these regulations. At the same time efforts should be made not to over-regulate, but to keep access to the market as open as possible. This is specially important for small firms and generic products. Because their efficacy and safety has already been documented, generic drugs should be registered through an abbreviated process focused on product quality. Reducing barriers to international trade in intermediates and formulations and harmonization of regulations at the regional level also tend to open markets to more competition.
The Uruguay Round of trade negotiations under the General Agreement on Tariffs and Trade concluded in 1994 with an important agreement on trade-related intellectual property rights (TRIPs). It establishes the obligation for all signatory countries to recognize patents on pharmaceuticals under stringent conditions, which entails a significant change in the basic rules of the markets of a number of countries. Industries in such countries, which used to produce pharmaceuticals patented in developed countries without the permission of the patent holder, will no longer be allowed to do so once the agreement is implemented. However, the agreement provides for a transitional period of 10 years and some possibilities, such as compulsory licences, to balance the exclusive rights conferred by patents and consequent higher prices with public health needs.

**Information**

More and better information is also needed to foster competition. Private and public institutions should disseminate information on the technical characteristics, prices and cost-effectiveness of medicines to physicians, pharmacists and patients.

**Incentives**

Incentives are devised to encourage consumers, health workers and the industry to take appropriate actions that are both economically and therapeutically beneficial. Monitoring is essential to ensure that incentives produce the intended effects. The following examples illustrate some possibilities:

- Public demand for lower priced drugs can be increased by publishing information on drug prices.
- Altering levels of cost-sharing can achieve a number of outcomes depending on the particular context of programmes or subsidy schemes. It may, for example, increase user awareness of cost, reduce wastage and increase the use of essential drugs compared to less useful drugs.

Methods of payment of health care providers can affect the way drugs are prescribed, dispensed, selected and used. Incentives to encourage cost-effective prescribing and a high quality of care by doctors can be designed by altering the method by which they are paid.

The provision of lower priced drugs by pharmacists can be encouraged by altering the ways in which they are remunerated. Possibilities include fixed salaries, capitation fees, and altering the formula for retail pricing or reimbursement.

A powerful way to foster price competition and cost-effectiveness is to link the available public or private finance with the selection of medicines.

Attention should be paid to incentives or practices that have undesirable consequences. For example, doctors who dispense may overprescribe. Policies that provide for lower retail mark-ups on essential drugs may actually encourage drug outlets to sell fewer essential drugs. Governments must identify incentives and practices that have negative effects and take necessary corrective action.

**Use of generic drugs to promote price competition**

The important economic characteristic of generic drugs is that - in contrast to
brand name drugs - their names identify the product, but not a single supplier. This opens the door to price competition among equal medicines, identified by international nonproprietary names, from different sources or suppliers.

The use of generic drugs may occur through generic prescribing, generic dispensing or generic substitution. Generic prescribing refers to the use of generic names by clinicians. Generic dispensing refers to the retail sale of drugs by generic name. Generic substitution is the practice of substituting a product, whether marketed under a brand name or generic name, by an equivalent product, usually a cheaper one, containing the same active principle(s) (30).

Generic prescribing, dispensing, and substitution are encouraged by many government health services to reduce drug costs and, thereby, to increase drug availability in the public sector. Countries may also encourage generic prescribing, dispensing, and substitution in the private sector to reduce drug prices and to increase consumer access. Retail pharmacists and licensed drug sellers sometimes prefer generic drugs because their lower wholesale price means lower operating costs for the drug outlet.

To promote the use of generic names, countries may require that: generic names be used in the formal education and in-service training of health professionals; brand name/generic name and generic name/brand name indexes be made available to health professionals; formulary manuals, drug bulletins, and other sources of drug information be based on generic names; and all pharmaceutical product package labels and accompanying information contain the accepted generic name, printed in a minimum type size compared to the brand name.

In addition, specific measures to promote access to generic drugs may include: generic prescription laws requiring that prescriptions be written exclusively by generic name; generic substitution laws that permit or require substitution of lower cost generic equivalents at the point of dispensing; restriction of reimbursement in social security or other insurance systems to low-cost generic equivalents, wherever available; and favourable retail fees for dispensing generic drugs. When there are multi-source products on the market, information to compare their prices is needed.

Certain constraints and concerns should be kept in mind by countries when promoting a policy of generic drug use. These include the need to ensure national quality control capability and regulatory effectiveness; to build confidence in generic drugs among providers of health care; and to inform the public and professionals adequately.

**Public and private drug financing arrangements**

Economic strategies can be considered in terms of two distinct drug financing environments: (a) public and institutional health services; and (b) private sector drug distribution and sale. Though there is overlap, specific strategies and policy options differ between the two environments.

**Public and institutional health services**

Drugs are generally made available as a routine part of primary health services and hospital care provided or financed by ministries of health, social security
systems, compulsory health insurance systems, or other institutional health services. The major financing issues that must be addressed by such institutions are efficiency, sources of financing, and cost containment.

Available financial resources can be used to achieve greater health impact through measures such as selection of cost-effective drugs, therapeutic guidelines, promoting rational drug use (see section 2.5), more efficient procurement and distribution, co-payments by patients, restricting reimbursement for drugs, and establishing per capita drug budgets.

**Private sector drug distribution and sale**
Direct purchase of drugs by consumers for self-medication or by prescription constitutes a large proportion - in some countries the majority - of drug expenditures. Strategies to promote access through the private sector may include increasing price competition (e.g. by generic substitution), controlling retail or wholesale prices, and providing incentives to encourage more equitable geographical distribution of pharmacy outlets.

**Drug financing mechanisms**

Possible sources of financing for pharmaceuticals include public financing, user charges, community financing, health insurance, and donor financing. In some countries health sector reform is resulting in a pluralistic approach in which different financing mechanisms serve different groups within the population. Those who are employed or are members of cooperative societies are covered by health insurance (e.g. social security); those who are not insured, but can afford it, purchase drugs and other health services out of their own pockets; and public financing may be targeted toward specific public health priorities.

Nevertheless, it is the responsibility of governments to ensure that drug financing mechanisms are managed in such a way as to achieve universal access to essential drugs. Health financing mechanisms may be evaluated and compared in terms of equity, efficiency, sustainability, and feasibility (31).

**Public financing**

Many countries maintain a commitment to public financing of health services, including essential drugs. Adequate public financing requires a knowledge of and a commitment to national health priorities that goes beyond the ministry of health to the entire government and, indeed, the entire society. Stable government financing for essential drugs may be facilitated by convincing decision-makers of the importance of health for national development. To generate commitment, ministries of health or analogous authorities need to justify their needs clearly and convincingly to the treasury and to the highest level of government. Good data therefore need to be collected through monitoring and evaluation of the national drug policy. Close ties and working arrangements with the national planning and finance authorities are also needed. The establishment of a council of senior policy-makers from the relevant ministries may result in better understanding of the importance of adequate health and drug budgets, and hence increased support.

Adherence to good pharmaceutical procurement practices and improvements in distribution systems not only lead to better use of available resources, but the resulting improvement in the ministry of health’s credibility may also lead to
increased allocations for drugs. Per capita drug budgets and systematic quantification of drug requirements may also contribute to stable financing. Where foreign exchange is limited, the highest priority should be the supply of essential drugs.

**User charges, co-payments, revolving drug funds, and community financing**

User charges and co-payments are becoming more common as a way to finance drugs, medical supplies, and other health care costs (32). However, such mechanisms should be designed so that the poor and certain other target groups are not denied access to essential health services, including drugs. Moreover, user charges and co-payments should be seen as a complement to government financing, not a substitute.

Experience with various forms of community financing has been mixed. Some programmes have been shown to increase access and to improve quality. But other programmes have been found to result in decreased use of health services, to achieve little or no improvement in quality, and to have high operating costs.

Critical factors in the success of these programmes have been local retention of revenue, effective management and accountability systems, community involvement, locally acceptable fee schedules, and adequate protection mechanisms. Protection mechanisms include waivers for those unable to pay and exemptions for antenatal care, treatment of sexually transmitted diseases, or other target conditions. Achieving these factors for success requires adequate management staff, systems development, and orientation of health staff and the public. Phased implementation can be very important.

Several other considerations are important in these programmes. Defining what is meant by "poor" presents practical problems that require local solutions. The use of drug fees to pay salaries may create incentives for over-prescribing. Fees should be structured to encourage and support the referral system.

**Health insurance**

Insurance schemes collect premiums from individuals or their employers to pay for health expenditures incurred by scheme members. This spreads the risk of health care costs across all members. Health insurance schemes include compulsory social health insurance, social security, private insurance (voluntary or through the employer), managed care (which links health care providers to insurers), and small-scale community health insurance.

Important factors in assessing the equity, feasibility, and efficiency of insurance programmes include the source of the premium (individual or employer), its level and affordability, the extent of the population covered, the extent to which essential drugs are covered, the financial viability of the programme, and the level of cost-sharing involved. Insurance programmes, whether compulsory or voluntary, require public supervision and must be accountable to their members.

**Donors and international loans**

External financing from bilateral or multilateral agencies may be used to allocate resources to high priority areas such as immunization or essential drugs for the neediest population groups. This form of revenue may also be important in some countries to finance the development and implementation of drug policy in
general or for specific areas such as the development of situation analyses and interventions to improve rational drug use.

Loans may contribute to long-term development of the human and physical infrastructure for health. However, they should not be used to finance the recurrent cost of drug supplies or other recurrent health care costs.

In the case of donor financing, governments need to ensure that a realistic transition is made to a continuing mechanism funded through a line item in the ministry of health budget or appropriate other private or institutional funding mechanisms. Careful evaluation of external financing at the individual project level and national level is needed.

Reaching the point of sustainability may require commitment by funding agencies for longer periods of time, say 10 - 15 years. For some countries, economic necessity may require dependency on an externally funded programme for a long period of time.

**Increasing value for money in the drug sector**

Various measures can be taken to increase value for money and to contain costs in the drug sector. These measures be applied to the pharmaceutical industry, the distribution network, health care providers, and consumers.

**Price regulations and negotiations**

Proper organization of the market and application of anti-trust (monopoly) laws should lead to price competition. However, if pharmaceutical markets do not become competitive, governments may choose to institute price controls. Price control may also be considered before a competitive pharmaceutical market has fully developed.

Control or regulation of pharmaceutical prices may be based on (a) actual costs (cost-plus pricing based on manufacturer's or importer's cost plus a fixed mark-up), (b) controlling companies' profit margins, or (c) comparison with prices in other countries or prices of other drugs in the same therapeutic category (yardstick, benchmark, or reference pricing). Once initial prices are established, decisions must then be made about price increases.

Price control has several limitations. The required information may not be available in some countries. Price controls may discriminate against cheaper, effective, older drugs, or create an incentive to raise the number of products. Finally, price controls require considerable government capacity for inspection and follow-up of the control mechanisms.

Direct price negotiation with the manufacturer may be justified for patented and other single-source medicines that have no therapeutic substitutes and that have important public health implications.

**Efficiency in drug management**

Good pharmaceutical procurement practices can substantially reduce drug costs to ministries of health and other health care institutions. These practices include the use of generic names, competitive procurement among qualified suppliers, and prompt payment. Distribution may be improved by introducing elements of
private sector management, by contracting transport services, or by arranging for
direct delivery by suppliers to major health institutions. The degree of
decentralization depends on the particular conditions of every country, but
decentralization of specific supply functions such as distribution may increase
efficiency.

Cost-effective drug selection and use
Selection of cost-effective drugs at the primary health care, hospital or national
level is a major component of cost control. Selective drug lists for public health
systems or private insurance include:

- Positive lists (essential drugs) setting criteria for new drugs to qualify for
  reimbursement.
- Negative lists, as in some industrialized countries, which exclude drugs from
  coverage under the health insurance system for therapeutic or financial reasons.

Promoting rational drug use may also help to control costs. Generic substitution
and promoting generic prescribing should be encouraged. Therapeutic committees
and clinical guidelines promote the economical use of drugs.

Reimbursement controls
A further means of controlling cost is to establish different levels of reimbursement
and to increase the proportion of the cost paid by the consumer for certain
products (those not included in the national essential drugs list, for example).

Expenditure budgetary ceilings
Budgetary ceilings may be used to contain drug expenditures in the public sector
and in national health insurance schemes. Care must be taken to ensure that such
restrictions do not result in reduced access for the poor.

Economic evaluation
Drug selection decisions and the establishment of standard treatments involve
judgements about relative therapeutic value. The economic evaluation of drugs is
a systematic method to identify which of a series of alternative therapies will
achieve medical objectives most cost-effectively. It forms part of a newly emerging
discipline called pharmaco-economics.

Economic evaluation is being used in some industrialized countries to determine
whether the magnitude of the benefit of a new drug justifies the cost and then to
subsidize those drugs that produce the greatest output in improved health in
return for the lowest cost.
Policy-makers are faced with a lack of unbiased and accurate information on the
trade-offs between competing goals. Economic evaluation is useful because it
offers a logical framework for considering a new drug for subsidy, for drug
formulary management, or for price-setting. Yet it is not a proven means of
budgetary control. It is a complex, time-consuming and resource-intensive
process. Frequent reassessment of decisions is necessary as more information
becomes available.

Though economic evaluation has been used for drug evaluation decisions in only a
limited number of industrialized countries, it has been used in developing
countries to assist in decisions on malaria control, diarrhoeal disease control,
immunization, the distribution of ivermectin, and other health activities.
2.7 Monitoring and evaluation of national drug policies

Indicators

When a country fixes its objectives for a national drug policy, it is advisable to establish a process of monitoring and evaluation so that progress in achieving the policy's objectives can be assessed. This provides the basis for any adjustment to the policy as it evolves. Once objectives are fixed - for example ensuring that drugs are of good quality and used rationally - a series of strategies is developed by which to implement the policy. Strategies may relate to all components of the policy or they may cover only high-priority components based on assessment of needs and available resources. Even if overall policy objectives have not been set, a process of monitoring and evaluation is very useful to measure the progress of chosen strategies.

Indicators are a tool to enable progress and achievements in the implementation of a drug policy to be measured. A manual of indicators for monitoring national drug policies has been developed by WHO (32). Other organizations and countries have also developed indicators (34, 35).

Indicators and monitoring systems are only worth while if they are used. Too often, in all countries, data are collected but never analysed; or they are analysed but never used to evaluate existing practices or policy. Results can be used to improve the performance of a drug policy in the following ways:

- To assess capacity to implement the various elements of a national drug policy.

- To monitor the processes by which a national drug policy is implemented and the changes over a period of time.

- To measure the policy's progress towards the achievement of objectives, allowing decision-makers to adjust strategies accordingly. Questions such as the following can be addressed: Are the basic structures in place, and are they functioning adequately? Which components are performing well, and which not? If measurement is done regularly over time, then it becomes possible to determine whether particular components have improved or declined in performance.

- To assess the priorities for implementation in the drug sector, together with the effectiveness of overall drug policy strategies. If one component of drug policy is performing poorly compared to other components, then it may be desirable to allocate more resources (both human and financial) to it, and thereby revise the relative priorities of different components, in an effort to improve implementation. In some cases, it may be necessary to change the strategy, for example by introducing a programme for the promotion of essential drugs, or by developing new pricing policies in order to encourage private distribution of essential drugs.

- To use in negotiations on drug policy among the various interested parties within a country, and also in policy discussions on health sector reform with
external donors and international agencies. For example, the consequences of macro-economic policy changes (such as devaluation) for the pharmaceutical system in particular and for the health system more broadly can be demonstrated. The data collected can allow health policy-makers to put their arguments more persuasively and coherently, to ensure that the health sector and the health status of vulnerable groups are not forgotten during times of economic reform.

- To compare drug policy performance across different countries, using appropriate methods for monitoring and evaluating the national drug policy. Cross-national comparisons can also assist national policy-makers in learning about innovative approaches that may be applicable in their own countries.

When monitoring a national drug policy, identifying appropriate data sources, determining how to collect the data, organizing the collection and analysing the results should be carefully planned. The quality of the information collected will affect the validity of the results and the appropriateness of the changes proposed.

The use of carefully selected, representative sentinel sites may facilitate the monitoring process. These facilities are asked to submit specific information to a central monitoring unit. Such data are promptly analysed, then fed back to submitting units, and a report is generated for decision-makers.

**Responsibilities**

A team at central level, most probably in the ministry of health or national drug authority, should be responsible for the monitoring system, i.e. for data collection, analysis and reporting. The final choice of indicators to be used for monitoring the national drug policy should be made at the beginning of the process. A description of the process is given in the WHO manual (33).

**Evaluation**

National drug policies should be thoroughly evaluated at regular intervals, e.g. every three to five years, by internal and external evaluators. The results of such an evaluation should be discussed in a national policy committee, comprising all interested parties. It may be useful for countries to publish the findings.

2.8 Research

Research is an essential feature of national strategies for improving health. It is carried out by a variety of public and private bodies, among them the research-based and the non-prescription pharmaceutical industry, universities, biomedical research institutes, social and economic research institutes, and consumers' associations. Research can be promoted and, to a certain extent, directed and coordinated by a variety of means, including intellectual stimulation, scientific and technological competition, and financial incentives, whether private or public. Coordinating mechanisms vary in nature: medical or health research councils, scientific research councils, and publicly or privately funded national institutes may all contribute to shaping priorities. In the drug field, two types of research are important: operational research, and drug research and development.
Operational research

Operational research is aimed at filling some of the many gaps in existing knowledge about the best means of selecting, procuring and distributing drugs, and their use by prescribers and consumers, and at finding solutions to the many problems faced in implementing national drug policies.

Operational research should lead to practical and cost-effective interventions and should support management decisions. In order to ensure that the results are actually used, the studies should be developed and executed in close collaboration with policy-makers in the ministry of health, the national essential drugs programme or other disease control programmes. An important part of national drug policy is therefore to draw the attention of all concerned in both the public and the private domains to the need for operational research that is relevant to the country’s main health problems. In some countries external funding and technical support may be needed to develop the protocols and interpret the findings.\(^1\)

Drug research and development

The nature and scope of drug research and development obviously vary according to the health problems, interests and capacities of each country. They involve, inter alia, fundamental research in molecular biology and chemistry, immunology and biotechnology, industrial research to convert scientific knowledge into useful technology, pharmacological and toxicological studies, and clinical and field trials of drugs and vaccines. A national drug policy can indicate research needs and priorities. Such needs include new, more effective, less toxic, and more stable drugs and vaccines for existing conditions, including, "orphan diseases" (diseases that affect relatively few people and for which the sale of drugs is therefore limited in quantity), and new drugs for newly emerging health problems such as HIV and drug-resistant infections. Drug research is expensive and fraught with uncertainty. Hence the cost factors involved and the proposed methods of financing have to be considered carefully before embarking on it.

Clinical trials should be undertaken in countries only if needed and if appropriate scientific facilities and regulations exist. They should be organized on the basis of scientific criteria and conducted in accordance with good clinical practice, following approval by the competent national authority (10, 38).

2.9 Human resources development

Development of a drug policy requires highly qualified and experienced professionals, including medical doctors, pharmacists, clinical pharmacologists and paramedical staff.

\(^1\) The WHO Action Programme on Essential Drugs has been active in strengthening countries’ capacities to conduct operational research through the training of researchers and the development of standard protocols, e.g. on injection practices research (36), on research on drug utilization in communities (37) and health facilities (22), and on indicators for monitoring national drug policies (34).
Lack of appropriate expertise to deal with particular aspects has been a decisive factor in the failure of some countries to achieve the objectives of a national drug policy. Human resources in sufficient numbers and with appropriate technical and professional capabilities are required to implement a national drug policy consistently. Human resources development is therefore one of the most important elements of a drug policy and should be given the highest priority in its implementation.

A national drug policy involves a wide range of skills. For each category of personnel, the nature and extent of their involvement in the national drug policy should be clearly and explicitly defined. This will determine the type and amount of orientation and training required for each professional group. An analysis of staffing needs should be carried out and arrangements made for the training and continuing education of both managerial and technical personnel.

Human resources development should make use of the available local educational and research institutions, with emphasis on the leading role of universities, hospitals and related training facilities. In bilateral and regional technical cooperation, including technical cooperation among countries, human resources development should receive top priority.

As drug regulation, marketing, distribution, prescribing and management involve several drug-related professions and sectors, a multisectoral and multidisciplinary approach should be adopted. Thus human resources development requires multisectoral coordination, involving both health administrations and educational institutions (including private institutions) at various levels. Professional organizations should be encouraged to participate fully, especially in organizing training sessions and courses.

Human resources development should include the following activities:

- Quantitative analysis of human resources needs.
- Human resources planning, including the establishment of new educational institutions and the sending of students and staff abroad, as appropriate, for graduate and postgraduate studies.
- Training of administrators, pharmacists, laboratory analysts, doctors, nurses and health volunteers.
- Organization of courses, such as courses for drug inspectors and the logistic management of drugs.
- Career development, including continuing education programmes in line with new scientific and technological developments, and the establishment of minimum educational and training requirements (e.g. for inspectors responsible for good manufacturing practices).

Comprehensive long-term, intermediate and short-term human resources development plans must be prepared, taking usual lead times in the education process into account.

Long-term plans for health personnel development are essential to ensure that training activities match personnel needs. National health personnel development plans should specify the major cadres of health personnel, the levels within each cadre, and the primary responsibilities of staff at each level. Information on health
financing, staff turnover, actual or estimated workloads at various levels of care, population growth, and other factors that influence health care demand must also be gathered. This information can then be combined into a long-term health personnel development plan that specifies intake, pre-service training, and in-service training. Such plans should cover health personnel requirements in both the public and the private sectors.

National collaborating networks

Collaboration between drug regulatory authorities and universities, research institutions, professional societies, and even individual experts benefits all those concerned. It can serve to introduce the principles of rational drug use and hence to promote their application.

Activities that need specialized expertise - for example, drug evaluation, drug monitoring, and drug information services, including the publication of drug bulletins - can be assigned to universities, research institutions and professional societies, thus creating national collaborating networks. These functions are very much in line with educational and research activities.

Teaching hospitals, including private institutions, are ideal for designation as training centres for drug information experts.

Role of experts in drug policy-making and regulation

Expertise is needed in different areas of national drug policy, such as policy analysis, management and finance; specific skills in such fields as cross-sectoral consultation are also required. This expertise may not be available within the governmental authority responsible for drug policy and regulation. Whenever possible, it should then be sought from other relevant sectors and from neighbouring countries. When there is a shortage of appropriate local experts in the country, it is advisable to send professionals for postgraduate studies abroad.

Education, training and courses

Policy-makers and administrative personnel need to be familiar with the financial, managerial and operational implications of the national drug policy. Both clinical staff - physicians, nurses, and paramedical personnel - and pharmacists need to be familiar with key policy issues that affect the supply and use of drugs, with the essential drugs concept, and with factors that influence rational drug use. Health providers at all levels, in particular at the provincial and district levels where the use of certain drugs (e.g. drugs for tropical diseases) is greatest, should be fully aware of the principles of rational use of drugs. Adequate time for training in these areas must be provided in formal and continuing education programmes. Curricula in medical schools should include adequate training in therapeutics, prescribing and pharmacology. This training will require the provision of locally appropriate training and reference material.

Manufacturing, procurement, storage, distribution and dispensing require qualified and experienced professionals. Newly graduated professionals are generally not ready to undertake these tasks effectively, and may need additional practice and training. For example, staff working as drug inspectors require a thorough knowledge of drug legislation, production and quality assurance.
The role of pharmacists

Because pharmacists are in a good position to promote the rational use of drugs, their role should receive increased attention. This calls for better integration and use of pharmacists within the health care system, e.g. in pharmacies, in drug and therapeutic committees, purchasing committees and hospital pharmacy services (including the activities of clinical pharmacists), in the dispensing of drugs, in information centres, in industry and in regulatory activities, thus broadening their health-related professional scope. Curricula for pharmacists should therefore be adjusted to allow for these new roles, taking the economic and managerial aspects also into consideration.

Motivation and continuing education

Long-term plans for human resources development are essential to ensure a balance between training activities and human resource needs. Career planning is important in helping to recruit personnel in government service and in preventing the loss of staff to the private sector.

Attendance at scientific meetings and continuing education programmes will motivate the scientific staff and support them in giving their best performance. Good motivation is essential for professional staff, who need a strong sense of personal integrity in order to serve the best interests of the public.

Wherever feasible, recent developments in computer technology should be utilized to broaden the coverage of continuing education programmes across the country. Computer technology may also be used for continuing education organized within regions.

2.10 Technical cooperation among countries

Technical cooperation among countries has been effective in strengthening national and regional policies and has led to the harmonization of legislation, regulations and guidelines on pharmaceuticals. Such technical cooperation - among developed countries alone, developed and developing countries jointly, or among developing countries alone - helps to make the most of limited resources, including human resources.

Following meetings on the role of pharmacists held in New Delhi in 1988 (39) and Tokyo in 1993 (40), the WHO Executive Board at its ninety-third session (1994) adopted resolution EB93.R12 on the role of the pharmacist in support of WHO’s revised drug strategy. Later that year, the Forty-seventh World Health Assembly adopted resolution WHA47.12. These resolutions recommended the recognition of the role of the pharmacist in the health care system, particularly in quality assurance and the safe and effective administration of medicines. They also called upon pharmacists and their professional associations to promote, in collaboration with other health professionals, the concept of pharmaceutical care as a means of furthering the rational use of drugs and of actively participating in illness prevention and health promotion.

The Director-General of WHO, in his report to the Forty-seventh World Health Assembly, highlighted the need for countries to recognize and strengthen the role of pharmacists within drug regulatory authorities, in pharmaceutical manufacturing facilities and in the community at large as a necessary prerequisite to assuring the quality of pharmaceutical and biological products both at the time of manufacture and within the distribution chain.
The following areas have proved appropriate for such cooperation:

- evaluation of drugs
- exchange of information
- reporting of adverse drug reactions
- quality assurance, and collaboration between regional and other quality control laboratories
- WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce
- pharmacopoeias and regional reference standards
- inspection of pharmaceutical plants
- transfer of technology
- research and development
- pooled procurement of drugs
- training and human resources development
- studies on drug classification and utilization
- computerization of drug regulatory information
- recognition of and response to emerging and re-emerging infectious diseases
- emergency situations.

Many countries have adopted national drug policies. Experience in the formulation and implementation of these policies and the results of multi-country studies to assess their impact can be shared with mutual benefit to cooperating countries.

**Regional and bilateral cooperation**

Various groups of countries - including the Association of South-East Asian Nations (ASEAN), the European Union (EU), the Nordic countries in Europe, the Maghreb countries in North Africa, the Gulf States, the Andean countries in South America, the Organization of African Unity (OAU) and the Common Market for Eastern and Southern Africa - provide examples of successful inter-country cooperation. Significant bilateral technical cooperation, of benefit particularly to developing countries, has taken place in the fields of technology transfer, establishment of drug quality control laboratories and distribution systems, and human resources training. For countries in the initial stages of development, international contacts and consultation can provide information and help to avoid the repetition of errors committed elsewhere. For developing countries, learning from each other through technical cooperation can be more effective and acceptable than other patterns of cooperation, as their circumstances and resources are more readily comparable.

International contacts can be pursued both through the participation of national agencies in international programmes and through informal contacts between individuals with similar interests and responsibilities. It is important that contacts should be at more than one level in the organization. Not only should the head of the agency know and exchange information with counterparts in a number of countries (41) but corresponding contacts should be encouraged between the heads of units responsible for drug evaluation, laboratory services, inspection, surveillance, and so on. These individuals should also make a point of learning
about the organizational units in international agencies and institutions that can provide information on specific subjects.

International organizations such as WHO can provide the stimulus and support for regional cooperation through international programmes. The national regulatory agency, as opposed to individuals, should participate as fully as possible in international programmes of interest to the agency. Some programmes will of necessity be on a bilateral basis, others being sponsored at the international level by such agencies as WHO, e.g. the WHO International Conferences of Drug Regulatory Authorities (ICDRA). Publications and newsletters such as WHO drug information, the monthly Pharmaceuticals newsletter (which includes a list of addresses of individuals in regulatory agencies) and Essential drugs monitor provide information on drugs and on technical cooperation.

The identification of centres of excellence for training in cooperating countries, which can take the lead in organizing and coordinating cooperative activities, has been found to be a successful strategy in regional cooperation.

The WHO collaborating centres in various countries have been useful in the exchange of information and as a mechanism for forming networks of similar institutions in many countries. Advantage should be taken of the modern communication technologies, including electronic mail, that are facilitating information exchange on a global level.

Examples of technical cooperation among countries

The Pharmaceutical Inspection Convention (PIC) and the Product Evaluation Report Scheme (PER)

Successful international cooperation schemes include the Pharmaceutical Inspection Convention (PIC) and the Product Evaluation Report Scheme (PER). The essence of PIC is the mutual recognition of good manufacturing practices inspection reports, while PER member states share information about evaluation and approval of new medicines. Both schemes develop and implement common guidelines.

ASEAN Cooperation Project in Pharmaceuticals

The formula for the success of the ASEAN Cooperation Project in Pharmaceuticals is the following:

- Similarities in language and cultural affinity of the majority of the cooperating countries.
- Consultative and participatory planning by all countries involved from the start, so that each feels that it is a true partner in the project.
- Technical, financial and organizational support from international bodies such as WHO and the United Nations Development Programme (UNDP), which has been necessary to initiate and sustain the project over the years.
- Choice of common high-priority areas for cooperation with an immediate and highly visible impact on each country’s aspirations for better health for its people.
- Continuing and sustained activities over a period, one lead country taking responsibility as coordinator for each project assigned to it, all other countries in the region participating.
- Dissemination and exchange of outputs and relevant information from the project to all participating countries.
- A political climate in the ASEAN region when the project began that was highly conducive to cooperation, with growing collaboration among Member States in all fields of endeavours - social, economic, technical and political.
- Absence of any significant opposition from any sector or vested interest in any of the participating countries.

International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

A unique example of harmonization is the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This activity is a series of conferences, expert working groups and steering committee meetings held among regulatory agencies and industry associations of the European Union, Japan and the USA. ICH harmonizes the scientific and technical aspects of product registration by preparing guidelines in the areas of safety, quality and efficacy and developing common approaches to various aspects of regulatory communication including terminology and data transfer. Official observers in ICH include Canada, the European Free Trade Association (EFTA), and WHO. WHO distributes draft and final documents to its Member States worldwide and conveys their views to ICH participants. Universally accepted guidelines for drug registration will achieve more economical use of human, animal and material resources and facilitate the global availability of drug products while maintaining safety, quality and efficacy as well as safeguards for the protection of human subjects and public health.
3. Process for establishing and implementing a national drug policy

3.1 Setting priorities

During the development of a drug policy, not every measure is feasible and choices need to be made at each level as to which are the most appropriate strategies and the most important activities for attaining the objectives of the policy. The range of strategies and activities that can be successfully implemented in a particular country depends closely on the pharmaceutical situation and the socioeconomic level of that country.

Priority-setting follows a qualitative and quantitative analysis of the health and pharmaceutical situation and the socioeconomic setting in the country. In most instances, much of the data required has been collated during the process of writing the national health policy. In the absence of such data, an analysis of the following is suggested:

1. Levels of health care - primary, secondary and tertiary, both public and private.

2. Health subsectors - universities, hospitals, professional associations, and pharmaceutical manufacturers and distributors.

3. Ministries and bodies with activities that may have an influence on the implementation of the policy - ministries of education, finance and planning, commerce, trade and industry, and justice, the central bank, and tax and customs authorities.

Data specifically concerning pharmaceutical activity should be sought. Existing legislation and regulations need to be critically examined.

Priority-setting should take into account the overall national health policy and the national development objectives. Constraints of human and financial resources define the options that can be pursued. The major problem may be the result of inadequate supply, poor accessibility, irrational use, poor regulatory control or poor quality of drugs. Priorities should be set according to the gravity of the problem. Objectives, cost-effective strategies and activities can then be suggested. The key institutions and partners that will play a role in implementing the policy also need to be identified.
3.2 Formulating a national drug policy

Designing or revising a policy to address persistent problems requires dialogue with the interests involved: the national and international pharmaceutical industry, the medical and pharmacy professions, the drug sellers, the nongovernmental organizations' community, the government bureaucracy, and international donors. The challenge arises as much from problems in identifying the substance of an appropriate pharmaceutical policy as it does from problems in constructing a process that will bring the various groups together in agreement.

Given the nature of the pharmaceutical sector and the different interests involved, attempts to change the policies can be expected. A lesson drawn from varying country experience is that national drug policies have the highest chance of success when a forum for open and frank discussions and involvement of all partners is provided. This could take the form of a national drug policy council, which could meet every three to six months, and which would comprise all interested parties. The objective of such a national drug policy council would be to discuss and review the overall policy.

Political will and a core group of motivated, full-time staff are the main ingredients for successful formulation of a national drug policy. This could be concentrated in a national drug policy secretariat, which would be responsible for coordination and monitoring of national drug policy related activities. For the key people involved in the formulation and implementation of the national drug policy, study visits to their counterparts in countries that have operational national drug policies would be valuable preparation.

The following aspects of national drug policy formulation are listed for guidance.

Organize the policy process

The ministry of health is the most appropriate department to take the lead in developing a national drug policy. The first step is to decide how the formulation of the policy will be achieved, who will be involved at the various stages, and how the needed financial resources will be obtained. A plan needs to be prepared that will outline the process and the final output. This preparatory phase can be done within the pharmaceutical department of the ministry of health with the support of a small committee that will participate in all the steps in policy formulation. The more the policy calls for change, the more need there will be for involving people. This should be assessed from the beginning as it has an impact on the amount of financial and human resources needed. The need for external assistance (from countries with experience in developing national drug policies, donors or WHO) also needs to be assessed at this stage.

Identify and analyse problems

The second task when formulating a policy is to make a thorough analysis of the main problems in order to set attainable objectives. There are various ways of undertaking this initial analysis. The best method is perhaps to bring together a small team of experts, including some who have performed similar studies in other countries, and who are capable of examining the situation systematically, in order to identify problems and recommend what must and what can be done, and what
approaches might be taken. The experts should not come just from the ministry of health - they may be from the health professions, from trade and industry, and from other government agencies (particularly the treasury), or they may be invited consultants from donors or WHO. Once recommendations have been formulated, they can be discussed in a multidisciplinary workshop which can prepare strategic advice to the government.

However ambitious it may sound in the early stages of drug policy development, the situation in the country as a whole should be constantly kept in mind. The national economic situation, for example, is a major factor leading in many countries to unsatisfactory drug supply. It therefore makes no sense to base reforms solely on demands for more government money, since that is not available. The ultimate solution that has to be developed should take such structural constraints into account.

Set goals and objectives

Once priority problems have been defined, priority objectives can be identified. In general, the objectives should derive from the main problems. For instance, if one of the priority problems is lack of access to essential drugs, one of the priority objectives should be to increase the accessibility of essential drugs. The selection of the strategies is more complex as it may involve decisions between very different problem-solving approaches. The basis for decisions should be clearly stated and should again derive from the situation analysis. This third step can be done in a small workshop involving the key policy-makers in the ministry of health. Once objectives and strategies have been outlined, they can be discussed with all the other interested parties, e.g. in the national drug policy council.

There is likely not to be full agreement among all the parties. Industry may have objections; the medical profession may have a point of view that differs from that of the pharmacy profession; any party that feels secure in the status quo may feel threatened by change. Not uncommonly, one government agency will disagree with another on objectives, approaches, or timetables. The important thing is to establish as much trust as possible, to identify matters on which consensus and compromise is possible, and to use these matters as the basis on which to proceed.

Draft the policy

After a thorough analysis of the situation has been made and the main goals, objectives and approaches have been outlined, a national drug policy should be set down in writing. The text may take any number of different forms, but in general it should include the general goal of the policy; in most countries this will be to ensure that safe, efficacious drugs of good quality are accessible and affordable to the entire population and that they are used rationally. The specific objectives should then be described, followed in each case by the strategy to be adopted. For example, to ensure that essential drugs are available in health facilities (objective), the policy might propose the creation of an autonomous procurement unit and the strengthening of drug management in health facilities (strategies).

This drafting of the policy can be done by the small committee set up at the beginning with the support of the people who performed the situation analysis. In certain cases, drafting is done in larger workshops, but it is preferable for the size of the group to remain small, as large groups are difficult to manage and have
problems in arriving at a coherent text. Members of the national drug policy council may be consulted during the process if needed.

While the draft national drug policy is being discussed and written, the related activities for inclusion in the implementation plan should already be noted.

Circulate and revise the policy

In order to get full support from all interested parties, the draft document should be progressively circulated for comments, first within the ministry of health, then in other government departments, and finally to relevant institutions and organizations outside the government, as well as to the private sector. Endorsement by sectors such as planning, finance, education and commerce is of particular importance since the success of decisions regarding registration, foreign exchange allocations, and human resources development will depend on the support of government officials outside the health sector. The final consensus-building process could take place in the national drug policy council or at a national drug policy consensus workshop.

Once this wide consultation is complete, the policy document can be finalized. Although formulation of the policy should involve all the partners, the ministry of health and the government have the overall responsibility for it.

Obtain formal endorsement for the policy

Depending on the country, the document can then be submitted to the cabinet or parliament for approval and political support, or it can be a ministry of health document that will serve as a basis for the implementation plans. Ensuring the support of the legislators may be useful, as the pharmaceutical law and regulations will often have to be updated. In some countries the entire national drug policy document has become law. Although this may demonstrate strong commitment on the part of the government, it is not always advantageous because it is often difficult to change a law once it has been enacted. It may be more practical to have only certain components of the national drug policy incorporated into a law or regulations.

Launch the policy

Promotion of the policy is as important as the other technical steps. This will require that it is backed by political will and endorsed by highly qualified people and opinion leaders. Information on the policy should be disseminated through a variety of channels, and draw on reliable and substantiated data. It should enable the media and the public to understand and be supportive of the policy aims and rationale, thus contributing to its successful implementation.

3.3 Implementing a national drug policy

Formulating a national drug policy is one thing; implementing it is another. Policy implementation is the execution of the approaches embodied in the policy through various plans and programmes. In the same way as for the formulation, given the multisectoral nature of pharmaceutical issues, and as early as possible, the ministry of health should reach a consensus with government departments on action plans
and their implementation in such fields as economics, commerce, industry, education, and foreign exchange. Failure to make such contacts will impede implementation.

Once their policy has been developed, countries have taken different approaches to implementation. Some prepare a five-year “master plan for the pharmaceutical sector” which outlines the approaches and activities in detail and specifies the budget and responsible departments. Such a plan allows for better coordination of donor inputs and facilitates follow-up and monitoring of the progress made in implementing the policy. Other countries have broken down the various strategies into a number of different plans for the departments involved. Still other countries have developed tools and guidelines to facilitate the implementation of the policy by the various partners.

In all cases, in order for the policy to succeed, governments need to be proactive and committed. A set of strategies that they could use might include:

- Selecting the appropriate timing and combination of approaches and methods of implementation. Not everything can be done at the same time. In one country, for example, the rules requiring generic labelling and promotion had to be put in place before generic prescribing and dispensing could be mandated. In practice, it proved necessary to have a one-year interval between the issue of the rules on generic labelling and those on dispensing. In this way, by the time doctors and pharmacists were required to work in generic terms, products in the pharmacies had already been generically labelled.

- Starting implementation in relatively easy areas to ensure initial high-visibility success. Perception of success is an important consideration. If the policy is perceived to have yielded significant positive results, it is likely to continue to receive support and collaboration from important sectors.

- Adopting a flexible policy. In certain cases, it may be necessary to postpone an activity in exchange for future cooperation. For example, when introducing a policy on drug selection, ministries may find it useful to spend more time and effort on discussions with prescribers than to impose measures that will be met with resistance.

- Using experts to vouch for the technical soundness of the policy. It is important that highly qualified and respected people collaborate in and support the implementation of the policy; these may be clinical pharmacologists, clinical specialists in the main hospitals and universities, international consultants, and so on.

- Mobilizing key groups such as consumers and the media. While this has worked in some countries, it may be difficult in other countries, for example where there is no consumers’ movement.

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13 Examples of such master plans are available from WHO's Action Programme on Essential Drugs.
• Creating constituencies favourable to the policy both inside and outside the government. This is a key to the success of the implementation and the long-term sustainability of the policy.

There is no best way to implement a national drug policy. In some countries, the implementation process is launched and managed directly from the department responsible for pharmaceutical services in the ministry of health, generally with the support of various committees dealing with different aspects of the policy. In other countries the national drug policy secretariat is formed within the drug regulatory authority. A potential problem with such structures is the limited human and financial resources allocated to these departments, which makes it difficult for them to be proactive and to coordinate all the partners. In addition, there may be too much focus on the pharmacy aspects and not enough on the broad public health aspects that should inform a national drug policy. The resources problem could be overcome by designating a national essential drugs programme, attached to the pharmacy department, to serve as national drug policy secretariat. Further possibilities are for the directorate of health services to be directly responsible for the policy, or for the minister of health to be responsible. These solutions may give more visibility to the policy.

3.4 Monitoring

Implementation of the national drug policy should be continuously monitored. WHO has developed a manual of indicators for monitoring national drug policies (33). These indicators can be modified to suit circumstances in individual countries (see section 2.7).

3.5 Evaluation

The national drug policy should be periodically evaluated (e.g. every five years). Independent consultants or professionals from other countries or WHO may be invited to complement a national evaluation team. The findings should be discussed with all participating parties in the national drug policy council, and the resulting report should be published. A new master plan may then be drafted as appropriate.
Part II: Contribution to updating the WHO guidelines for developing national drug policies

References


