

How to develop and implement a national drug policy

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The world pharmaceuticals market has witnessed an increase in the number of pharmaceutical products^a circulating worldwide, leading to a rapid growth in both medicines consumption and expenditure. However WHO estimates that, as of 1997, at least one-third of the world's population still lacks access to essential medicines, either because these are not available or are too expensive, or because there are no adequate facilities or trained professionals to prescribe them. In poorer areas of Asia and Africa this figure may be as high as one-half. As a result, millions of children and adults die or suffer needlessly, although their disease could have been prevented or treated with cost-effective and inexpensive essential medicines.

Experience in many countries has shown that these complicated and interdependent problems can best be addressed within a common framework, as piecemeal approaches can leave important problems unsolved and often fail. In addition, the different policy objectives are sometimes contradictory, and so are the interests of some of the stakeholders. On the basis of this experience, WHO recommends that all countries formulate and implement a comprehensive national drug policy (NDP). A policy is not static and will usually evolve over time. Most countries will need to revise their policies within five years.

What is a national drug policy?

A national drug policy is a commitment to a goal and a guide for action. It expresses and prioritizes the medium- to long-term goals set by the government for the pharmaceutical sector, and identifies the main strategies for attaining them. It provides a framework within which the activities of the pharmaceutical sector can be coordinated. It covers both the public and the private sectors, and involves all the main actors in the pharmaceutical field.

A national drug policy, presented and printed as an official government statement, is important because it acts as a formal record of aspirations, aims, decisions and commitments. Without such a formal policy document there may be no general overview of what

is needed; as a result, some government measures may conflict with others, because the various goals and responsibilities are not clearly defined and understood. The policy document should be developed through a systematic process of consultation with all interested parties. In this process the objectives must be defined, priorities must be set, strategies must be developed and commitment built.

Progress in developing and implementing national drug policies has been impressive since the concept was launched in the mid-seventies. By 1999, 66 countries had formulated or updated a national drug policy within the previous 10 years, compared with 14 countries in 1989. A further 41 countries were in the process of developing a policy or had developed one more than 10 years ago.

Box 1 Why is a national drug policy needed?

- To present a formal record of values, aspirations, aims, decisions and medium- to long-term government commitments;
- To define the national goals and objectives for the pharmaceutical sector, and set priorities;
- To identify the strategies needed to meet those objectives, and identify the various actors responsible for implementing the main components of the policy;
- To create a forum for national discussions on these issues.

The consultations and national discussions that lead to the production of the drug policy document are very important, as they create a mechanism to bring all parties together and achieve a sense of collective ownership of the final policy. This is crucial in view of the national effort that will later be necessary to implement the policy. The policy process is just as important as the policy document.

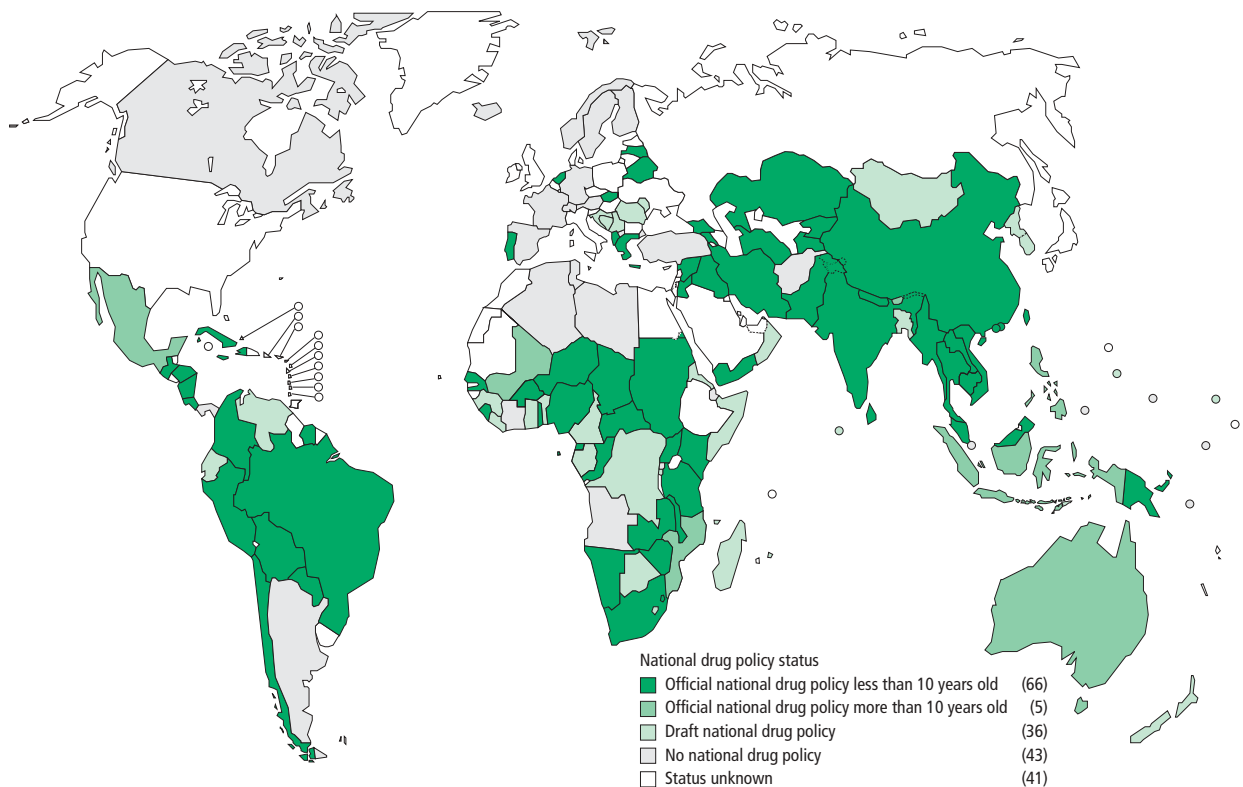
Objectives of a national drug policy

In the broadest sense a national drug policy should promote equity and sustainability of the pharmaceutical sector. The general objectives of a national drug policy are to ensure:

^a Throughout this document, the words 'drug', 'medicine' and 'pharmaceutical product' are used interchangeably.



Figure 1 By the end of 1999 over 100 countries had a national drug policy



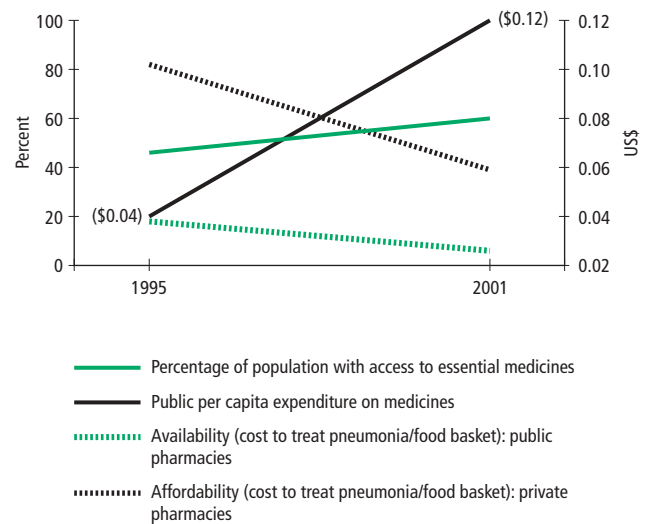
- Access: equitable availability and affordability of essential medicines, including traditional medicine;
- Quality: the quality, safety and efficacy of all medicines;
- Rational use: the promotion of therapeutically sound and cost-effective use of medicines by health professionals and consumers.

The more specific goals and objectives of a national policy will depend upon the country situation, the national health policy and political priorities set by the government. In addition to health-related goals there may be others, such as economic goals. For example, an additional objective may be to increase national pharmaceutical production capacity. It is critical that all the drug policy objectives are explicit, so that the roles of the public and private sectors and of the various ministries (health, finance, trade and industry) and government bodies (such as the drug regulatory authority) can be specified.

A drug policy can have a rapidly noticeable impact. For example, Chad adopted its drug policy and developed an implementation plan in 1995. Based on the results of the baseline survey carried out at that time, the national drug policy and its implementation plan focused on two strategies to improve access to

essential medicines: (1) appropriate selection and use of generic drugs, and (2) improved drug procurement and management through training, central medical store, and regional bulk procurement. In six years, the policy has had a significant impact (see Figure 2).

Figure 2 Impact of national drug policy in Chad, 1995–2001



The essential medicine concept is central to a national drug policy

The essential medicines concept is a global concept that can be applied in any country, in the private and public sectors and at different levels of the health care system. It promotes equity and helps to set priorities for the health care system. The core of the concept is that the use of a limited number of carefully selected medicines based on agreed clinical guidelines leads to a better supply of medicines, to more rational prescribing and to lower costs. There is substantial evidence that the use of national lists of essential medicines has contributed to an improvement in the quality of care and to a considerable saving in medicine costs.

The national drug policy process

A national drug policy involves a complex process of development, implementation and monitoring. First, the policy development process results in the formulation of the national drug policy. Second, strategies and activities aimed at achieving policy objectives are implemented by the various parties. Finally, the effect of these activities is monitored and

Box 2 The policy process (check list for policy makers)

Steps in formulation

- Organize the policy process
- Identify the main problems and stakeholders
- Make a detailed situation analysis
- Set goals and objectives
- Draft the text of the policy
- Circulate and revise the draft policy
- Secure formal endorsement of the policy
- Launch the national drug policy

Implementation

- Define priorities for implementation
- Develop a 3–5 year implementation plan including
 - **What** needs to be done?
 - **Who** is responsible?
 - **How much** is required for the budget?
 - **When** will the activity be carried out?
- Break down the implementation plan into annual work plans

Monitoring and evaluation

- Identify questions relevant for management decisions
- Limit data collection to data likely to be used
- Establish a reliable data collection system (plans for trained staff and resources)
- Share the data

the programme adjusted if necessary. Throughout the process careful planning and the involvement of all parties are needed, and the political dynamics have to be considered at all times.

Throughout the policy process there should be consultation, dialogue and negotiations with all interested groups and stakeholders. These include other ministries (education, trade, industry), doctors, pharmacists and nurses, local and international pharmaceutical industries, drug sellers, academia, nongovernmental organizations, professional associations and consumer groups. It is also important to consult with provincial and district personnel, and traditional and herbal medicine practitioners. Other government agencies, such as the drug regulatory agency, government sponsored health care schemes and insurance companies, must be involved.

Box 3 The national drug policy of South Africa

The National Drug Policy of South Africa was developed by the Department of Health over a two-year period through a large number of consultative meetings involving political parties, other ministries, academia, provincial and district representatives, professional bodies, the pharmaceutical industry and consumer representatives. The final document was adopted by Cabinet and presented to Parliament in June 1996; this formed the basis for a comprehensive five-year Implementation Plan. Part of its success was due to the political “window of opportunity” immediately after the end of apartheid in 1994.

Key components of a national drug policy

A national drug policy is a comprehensive framework in which each component plays an important role in achieving one or more of the general objectives of the policy (access, quality and rational use). The policy should balance the various goals and objectives, creating a complete and consistent entity. For example, access to essential medicines can only be achieved through rational selection, affordable prices, sustainable financing and reliable health and supply systems. Each of the four components of the “access framework” is essential but not sufficient in itself to ensure access. Similarly, rational use of medicines depends on many factors, such as rational selection, regulatory measures, educational strategies and financial incentives. Table 1 lists the key components of a national drug policy. It shows how they relate to the three main objectives of the policy and that most components cannot be linked to one objective only.



Table 1 Components of a national drug policy, linked to key policy objectives

Components:	Objectives:		
	Access	Quality	Rational use
Selection of essential medicines	X	(X)	X
Affordability	X		
Financing options	X		
Supply systems	X		(X)
Regulation and quality assurance		X	X
Rational use			X
Research	X	X	X
Human resources	X	X	X
Monitoring and evaluation	X	X	X

X = direct link; (X) = indirect link

Selection of essential medicines

No public sector or health insurance system can afford to supply or reimburse all medicines that are available on the market. The selection of essential medicines helps setting priorities for all aspects of the pharmaceutical system. When linked to national clinical guidelines, it is a crucial step in ensuring access to essential medicines and in promoting rational use of medicines. Key policy issues are:

- adoption of the essential medicines concept to identify priorities for government involvement in the pharmaceutical sector;
- selection of essential medicines in a two-step process: (1) market approval; (2) selection of essential medicines relevant to the national morbidity pattern;
- defining the selection criteria (i.e. sound and adequate evidence, cost-effectiveness, etc.);
- defining the selection process (i.e. appointment of a standing committee, etc.);
- ensuring a selection mechanism for traditional and herbal medicines.

Affordability

Affordable prices are an important prerequisite for ensuring access to essential medicines in the public and private sectors. This issue is important because resistance to well-known antibiotics, which are widely available as generic products, is increasing. New essential medicines for the treatment of some infectious diseases, such as malaria, tuberculosis and HIV/AIDS, are often very costly. Key policy issues are:

- government commitment to ensuring access through increased affordability;
- for all medicines: removal or reduction of taxes and tariffs on essential medicines; control of distribution margins; pricing policy;
- for multi-source products (generic medicines and branded generics): promotion of competition through generic policies, generic substitution and good procurement practices;

- for single-source products: price negotiations, competition through price information and therapeutic substitution, and TRIPS-compliant measures such as compulsory licensing, “early workings” of patented medicines for generic manufacturers and parallel imports.

Financing options

Ensuring stable and adequate financing for health care is becoming increasingly difficult in the face of economic pressures, continued population growth and the growing burden of disease. Countries vary greatly with respect to income levels, population, health care expenditure and national spending on pharmaceuticals which may vary from US\$ 2 to US\$ 400 per capita per year. In countries where government policies are not geared to protecting the needs of the poorest people, the poor may be denied access to drugs. Key policy issues are:

- commitment to measures to improve efficiency and reduce waste;
- increased government funding for priority diseases, and the poor and disadvantaged;
- promotion of medicine reimbursement as part of public and private health insurance schemes;
- use of user charges only as a temporary drug financing option;
- limiting the use of development loans within identified national priorities;
- following national or WHO guidelines for medicine donations.

Supply systems

Another essential component is a reliable supply system. Various types of supply systems exist which vary considerably with respect to the role of the private sector and the incentives for efficiency. But whatever system is developed, its aim is to ensure continued availability of essential medicines with low rates of stock-outs and low costs of medicines. Key policy issues are to:

- promoting a public-private mix in medicine supply and distribution systems;
- committing to good pharmaceutical procurement practices in the public sector;
- publishing price information on raw materials and finished products;
- ensuring medicine supply systems in acute emergencies;
- carrying out inventory control, and taking measures for prevention of theft and waste;
- ensuring disposal of unwanted or expired medicines.

Regulation and quality assurance

The drug regulatory authority is the agency that develops and implements most of the legislation and regulations on pharmaceuticals, to ensure the quality, safety and efficacy of medicines, and the accuracy of product information. This is done by making certain that the manufacture, procurement,

import, export, distribution, supply and sale of drugs, product promotion and advertising, and clinical trials are carried out according to specified standards.

Drug regulation is a complex task, with many stakeholders and vested interests involved. For this reason there are a number of basic requirements:

- Government commitment to drug regulation, including the need to ensure a sound legal basis and adequate human and financial resources;
- Independence of the regulatory authority to ensure that there is no conflict of interest;
- Commitment to good manufacturing practices, inspection and law enforcement;
- Regulation of traditional and herbal medicines;
- Ensuring adverse drug reaction monitoring systems;
- Commitment to regulation of information and drug promotion;
- International exchange of information.

Rational use

The rational use of medicines means that patients receive medicines appropriate for their clinical needs, in doses that meet their individual requirements, for an adequate period of time, and at the lowest cost to them and their community. Irrational drug use by prescribers and consumers is a very complex and widespread problem, which calls for the implementation of many different interventions at the same time. Efforts to promote rational use of medicines should also cover the use of traditional and herbal medicines. Key policy issues include:

- Mandated multidisciplinary national body to coordinate medicine use policies;
- Development of clinical guidelines as the basis for the selection of essential medicines and training of health professionals;
- Problem-based training in pharmacotherapy in undergraduate training;
- Continuing in-service medical education as a licensure requirement;
- Independent and unbiased medicine information;
- Public education about medicines;
- Avoidance of perverse financial incentives to prescribers and dispensers.

Research

There are two categories of research that are of particular importance in the development and implementation of national drug policies:

- **Operational research** in medicine access, quality and rational use is aimed at better understanding of factors affecting drug use, and identifying the best methods of selecting, procuring, distributing and correctly using drugs. It is an essential tool in assessing the drug policy's impact and its results underpin management decisions.
- **Drug development and clinical research** includes research into new drugs, drugs for neglected infectious diseases, new dosage

forms and manufacturing processes, and clinical assessments of efficacy and safety.

Human resources development

Implementing a national drug policy and achieving its objectives depend on people. They will implement the policy only if they understand its rationale and objectives, when they are trained to do their jobs well, paid adequate wages, and motivated to maintain high standards. Lack of appropriate expertise has been a decisive factor in the failure of some countries to achieve the objectives of their national drug policy. Key policy issues are:

- government responsibility for planning and overseeing the development, training, team building and career planning of human resources needed for the pharmaceutical sector;
- definition of minimum education and training requirements for each category of staff;
- the need for external technical cooperation (national and international).

Monitoring and evaluation

Monitoring and evaluation are essential components of a national drug policy. Provisions for monitoring and evaluation need to be included in the policy itself. Adequate staff and an operating budget also need to be set aside. Key indicators for each component of the policy should be defined. These indicators can be measured to assess progress. Key aspects of a national drug policy include:

- explicit government commitment to the principles of monitoring and evaluation;
- baseline survey of the whole country carried out early in the implementation of the policy;
- monitoring of the pharmaceutical sector through regular indicator-based surveys;
- independent external evaluation of the impact of the policy on all sectors of the community and the economy, preferably every 2 to 3 years.

Box 4 The national medicines policy of Australia

In the 1990s the Government of Australia carried out several activities which could be considered as components of a national drug policy. Examples are:

- promoting equitable access to health care for its citizens through a carefully designed system of pharmaceutical benefits
 - promoting the rational use of medicines through treatment guidelines (e.g. antibiotic guidelines), prescriber training programmes, public education
 - promoting a viable national pharmaceutical industry
- However, it was only in 2000 that these and other efforts were integrated into the National Medicines Policy in Australia – making Australia one of the first developed countries with an official comprehensive national drug policy.



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The documents marked with * are also available on <http://www.who.int/medicines/>

Contacts in WHO Regional Offices:

Regional Office for Africa:

Dr Jean-Marie Trapsida
Coordinator, Essential Drugs and Medicines Policy
Tel: +263 4 742829 E-mail: trapsidaj@afro.who.int

Regional Office for the Americas:

Dr Rosario D'Alessio
Regional Adviser for Pharmaceuticals
Tel: +1 202 974 3282 E-mail: dalessir@paho.org

Regional Office for the Eastern Mediterranean:

Mr Peter Graaff
Regional Adviser, Pharmaceuticals
Tel: +20 3 483 0096 E-mail: graaftp@emro.who.int

Regional Office for Europe:

Mr Kees de Joncheere
Pharmaceuticals
Tel: +45 3 917 1432 E-mail: cjo@who.dk

Regional Office for South-East Asia:

Dr Krisantha Weerasuriya
Regional Adviser, Essential Drugs and Medicines Policy
Tel: +91 11 331 7804 E-mail: weerasuriyak@whosea.org

Regional Office for the Western Pacific:

Dr Budiono Santoso
Regional Adviser
Tel: +63 2 528 9848 E-mail: santosob@wpro.who.int

Contacts at WHO Headquarters:

Essential Drugs and Medicines Policy Health Technology and Pharmaceuticals Cluster WHO Headquarters, Geneva, Switzerland:

Dr Jonathan Quick
Director, Essential Drugs and Medicines Policy Department
Tel: +41 22 791 4443 E-mail: quickj@who.int

Dr Hans Hogerzeil
Team Coordinator, Policy, Access and Rational Use
Tel: +41 22 791 3528 E-mail: hogerzeilh@who.int

Dr Lembit Rägo
Team Coordinator, Quality and Safety: Medicines
Tel: +41 22 791 4420 E-mail: ragol@who.int

Dr Germán Velásquez
Team Coordinator, Drug Action Programme
Tel: +41 22 791 3509 E-mail: velasquezg@who.int

Dr Xiaorui Zhang
Team Coordinator, Traditional Medicine
Tel: +41 22 791 3639 E-mail: zhangx@who.int

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