Guidelines for the formulation, implementation, monitoring and evaluation of national drug policies

World Health Organization
Regional Office for Africa
Harare
Guidelines for the formulation, implementation, monitoring and evaluation of national drug policies

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<th>Description</th>
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<tbody>
<tr>
<td>AFRO</td>
<td>WHO Regional Office for Africa</td>
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<tr>
<td>CMS</td>
<td>Central Medical Stores</td>
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<td>DAP</td>
<td>Action Programme on Essential Drugs</td>
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<td>DRA</td>
<td>Drug Regulatory Authority</td>
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<td>EDL</td>
<td>Essential Drugs List</td>
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<td>EDM</td>
<td>Essential Drugs and Medicines Policies</td>
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<tr>
<td>IEC</td>
<td>Information, Education and Communication</td>
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<tr>
<td>INN</td>
<td>International Non-proprietary Name</td>
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<tr>
<td>MAC</td>
<td>Management Advisory Committee</td>
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<td>MOH</td>
<td>Ministry of Health</td>
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<td>NDP</td>
<td>National Drug Policy</td>
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<td>NDPIP</td>
<td>National Drug Policy Implementation Plan</td>
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<tr>
<td>NGO</td>
<td>Nongovernmental Organization</td>
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<td>NHP</td>
<td>National Health Policy</td>
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<td>PAP</td>
<td>Priority Action Plan</td>
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<td>STG</td>
<td>Standard Treatment Guidelines</td>
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<td>World Health Organization</td>
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PREFACE

In line with WHO's revised strategy on essential drugs, the WHO Regional Office for Africa (AFRO) and the Action Programme on Essential Drugs (DAP), organized three workshops in 1993 to discuss the process of the formulation and implementation of national drug policies (NDPs).

In order to accelerate the development of national drug policies in Africa where coverage in essential drugs is low, regional experts drafted a guide for the formulation and implementation of NDPs based on experiences of several developing countries (Benin, Burundi, Guinea, Malawi, Nigeria, Sudan, Tanzania and Yemen). This was done during the first workshop, which was held in Brazzaville from 26-30 April 1993.

The second workshop was organized in Cotonou from 21-25 June 1993 to discuss and review the above mentioned draft document. This workshop gathered directors of health services and directors of pharmaceutical services from 11 Francophone and Lusophone countries of the West African sub-region. A similar workshop was organized in Brazzaville from 20-24 September 1993 for directors of health services and directors of pharmaceutical services from 15 countries of the Central and Southern African sub-region. The draft document was discussed and reviewed during both meetings. It was then finalized and distributed to all AFRO Member States.

Most countries in the African Region now have an NDP as well as its implementation plan. However, after 5 years, there was a need to know whether the guidelines developed in 1993 were useful. There was a need to know the difficulties faced by Member States in their use and possible improvements for the new edition. There was also a need to assess if NDPs are being implemented and monitored and eventual problems met in the formulation, implementation and monitoring processes. To respond to these concerns, AFRO in collaboration with the Essential Drugs and other Medicines Department (EDM1) organized two workshops: one for the Anglophone African countries in Harare, from 23-27 November 1998; and another for Francophone and Lusophone countries, in Douala, from 10-15 May 1999. The reports of these workshops are available and can be obtained from AFRO on request.

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1 EDM = Essential Drugs and Medicines Policies includes the former Action Programme on Essential Drugs (DAP)
The participants of the two workshops found the guidelines very useful in the formulation and implementation of the NDP. However, there was a need to have a third part to provide guidance on monitoring and evaluation of NDPs. The participants made several important comments, which were taken into account in the present edition organized in the following three parts:

Part I - Guide I: Formulation and Implementation of a National Drug Policy;

Part II - Guide II: Implementation of a National Drug Policy;


The document also gives a list of definitions of usual terms linked to the formulation and implementation of an NDP and for the development of an NDPIP. Bibliographical references are also provided at the end of the document to assist national experts involved in the formulation and implementation of an NDP and development of an NDPIP, and for those wishing to improve their knowledge in the proposed methodology and planning techniques.

This document is intended for use by Ministry of Health (MOH) officials dealing with drug problems, members of the national drug committee, experts and professionals as well as other agencies involved in the national pharmaceutical sector.
GUIDE I

FORMULATION AND IMPLEMENTATION OF A NATIONAL DRUG POLICY
1. INTRODUCTION TO GUIDE I

Following the recommendations of the Thirty-ninth World Health Assembly (5-16 May 1986), the World Health Organization (WHO) has provided technical and financial support to Member States to formulate and implement National Drug Policies (NDP).

In 1992, a situation analysis undertaken by the Action Programme on Essential Drugs (DAP) showed that most countries had difficulties in ensuring the availability, accessibility and rational use of essential drugs. One of the causes of these difficulties is the lack of a written NDP. It was found that only 22 out of the 46 Member States of the African Region had a written NDP. However, there has been an improvement on this situation. In 1998, 33 countries of the African Region, among which 14 were francophone, had a written NDP document.

WHO Member States wanted to fulfil their responsibility to ensure a sufficient supply of good quality, safe and efficacious essential drugs at low cost. However, most of these countries did not have access to a practical methodological manual for the formulation and the implementation of a NDP. A meeting of experts from 10 countries held in Brazzaville, 26-30 April 1993, and two regional workshops respectively held in Cotonou, June 1993 and in Brazzaville, September 1993, led to the publication of a practical manual in 1994, to facilitate the process of formulation of NDPs. Directors of health services and of pharmaceutical services from 26 countries attended these workshops.

This guide was based on the experiences from several developing countries and it constituted a methodological manual that aimed at helping Governments to formulate and to implement NDPs in the context of their national health policies. The guide was not a model of a NDP but it described the processes to formulate and to implement a NDP taking into account the characteristics and specific problems of a particular country.

After five years of use of the guide in various Member States of the African Region, the Regional Office felt the need to assess the usefulness of this guide in the formulation and implementation of NDPs. Two meetings were therefore organized, bringing together directors of health services, and directors of pharmaceutical and medical services involved in the development of NDPs. These meetings were held in Harare, 23-27 November 1998 and in Douala, 10-15 May 1999.
The present guide is the result of the recommendations made by participants in order to improve the usefulness and practicality of the guide in the formulation and implementation of NDPs. It contains fundamental elements for the formulation of a NDP and also describes how to implement a NDP.

2. **THE FORMULATION OF A NATIONAL DRUG POLICY**

2.1 **What is a National Drug Policy?**

A National Drug Policy is both a commitment to a goal and a guide for action. It expresses and prioritizes the 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 should include both the public and private sectors and the main actors in the pharmaceutical area.

The basis of any policy is a body of values, norms, standards and principles that guide decisions, strategies and actions. A drug policy is a global orientation with objectives and strategies to be undertaken to improve the national pharmaceutical sector, in particular the availability, the accessibility, and the rational use of good quality, essential drugs at affordable cost.

2.2 **Objectives of a National Drug Policy**

The objectives of a NDP are to improve access to essential drugs by making them available and affordable; to ensure the safety, efficacy and quality of drugs available in the country, and to promote their rational use. The more specific goals and objectives of a NDP will depend upon the country situation, upon broader health policy and upon priorities set by a Government.

2.3 **NDP as part of a National Health Policy**

A National Drug Policy is developed within the framework of a given health care system and in the context of a national health policy. The goals of the NDP should be consistent with broader health objectives and implementation of the drug policy should
help to achieve these health care objectives. A National Drug Policy will also affect the existing health policy and the way in which health services are regarded. Health services lose their credibility if there is an inadequate supply of drugs. The implementation of an effective drug policy will help to promote confidence and participation in health services.

2.4 Why have a National Drug Policy?

Health is a fundamental human right: Access to health care, including essential drugs, is essential to realizing this right. Drugs play a crucial role in health care; they offer a simple, cost-effective answer to many health problems if they are available, affordable and properly used.

Lack of essential drugs: An increasing number of pharmaceutical products are available on the world market, but many people throughout the world do not have access to them. Millions of children and adults die each year from diseases which can be prevented or treated with inexpensive essential drugs.

Problems in drug quality: Substandard and fake products are common in many countries. Inappropriate handling and distribution can also alter the quality of drugs. All these can result in serious health consequences and waste of resources.

Irrational use of drugs: Many people buy, or are prescribed and dispensed, drugs which are not appropriate to their needs. Some use several drugs when only one would do. Others use drugs which carry unnecessary risks. The irrational use of drugs is the cause of unnecessary ill-health and suffering; it also leads to a waste of limited resources.

Persistent problems and new challenges: To understand the above mentioned, it is necessary to look at the characteristics of the drug market, and the attitudes and behaviour of government, prescribers, dispensers, consumers and the drug industry. Health sector reforms, structural adjustment policies, trends towards liberalization, and reorganization of global trade and tariff agreements have further complicated the situation in many countries making it hard to achieve more equity in health.

Changes in the patterns of disease and drug demand also present countries with major challenges, e.g. AIDS, emerging and re-emerging diseases, and drug resistance.
A common framework to solve problems in pharmaceuticals is recommended through the formulation of a NDP.

A drug policy is needed to determine standards and values which will guide actions in the drug sector.

- A drug policy is needed to define national objectives which should be met.
- A drug policy is required to identify which strategies will be pursued to meet these objectives.

2.5 How to formulate a National Drug Policy?

The formulation of a NDP has 10 main phases. These phases are interconnected and they are schematically presented in Fig. 1. At the centre of these phases is the need for a permanent government political commitment to support the process.
FIG. 1: PHASES IN THE FORMULATION OF A NATIONAL DRUG POLICY

1. ESTABLISHMENT OF A WORKING GROUP

2. SITUATION ANALYSIS

3. FORMULATION OF DRAFT NDP

4. WIDE CIRCULATION OF THE DRAFT NDP

5. CONSENSUS WORKSHOP ON NDP

6. FINALIZATION OF THE NDP DOCUMENT

7. GOVERNMENT APPROVAL OF THE NDP

8. PUBLICATION OF THE NDP DOCUMENT

9. LAUNCHING OF THE NDP

10. PLANNING OF NDP IMPLEMENTATION

GOVERNMENT POLITICAL COMMITMENT
POLICY

2.5.1 Phase 1 - Establishment of a working group

Experience has shown that political commitment often takes place when a crisis occurs in the national pharmaceutical sector (e.g., lack of vital drugs, drug price increases, frequent shortages, economic crisis like inflation, devaluation, etc.). However, this does not have to be so.

The Ministry of Health expresses its political commitment by establishing a working group composed of multisectoral (NGOs, private sector and government) and interdisciplinary experts such as pharmacists, physicians, managers, health economists and planners. Sub-working groups in specific areas should be created and must include experts in specific subject area. These sub-groups can seek the advice of external experts.

To render the working group operational, the Ministry of Health should define its terms of reference and should provide the required resources to formulate the NDP. If the Ministry of Health does not have these resources, requests for financial support may be addressed to bilateral or multilateral aid agencies.

2.5.2 Phase 2 - Analysis of the country’s drug situation

The working group collects all necessary data on the drug situation in the country. This analysis should cover the following components of the pharmaceutical sector:

- Drug legislation and regulation;
- Drug regulatory authority;
- Selection of drugs and pharmaceutical products;
- Drug supply;
- Cost of drugs and pricing policy;
- Pharmaceutical quality assurance;
- Rational drug use;
- Mode and source of drug financing and financial resources allocated to drugs;
• Human resources development in the pharmaceutical sector;
• Drug information and promotion;
• Research and development;
• Technical cooperation among countries;
• Traditional medicine.

The working group analyses all available data and identifies the weaknesses and the strengths of the pharmaceutical sector, with particular emphasis on the priority problems identified in the sector.

2.5.3 Phase 3 - Formulation of draft National Drug Policy

On the basis of the data collected and analysed in phase 2, the working group prepares a draft NDP document, which contains the following main chapters:

2.5.3.1 Introduction

The introduction consists of a short description of the geographic, economic, epidemiological, social and demographic characteristics of the country. It also contains a summary of the contents of the NDP document. It describes the relation between a drug policy and a health policy and its contribution to the NHP objectives.

2.5.3.2 History and situation of the pharmaceutical sector

This chapter briefly describes the current situation of the drug sector as well as policies and the institutional and operational strategies adopted during the preceding years in order to solve drug issues. The chapter also presents the priority problems identified in the national pharmaceutical sector, which will be tackled by the NDP.
2.5.3.3 **Preamble**

The NDP document is a government declaration. The preamble recalls the following points:

- The importance that it gives to the citizens’ health, eventually with reference to the country’s constitution and other legal documents;
- The importance of a healthy population in the country’s economic and social development;
- The critical place and the role that drugs play in the health system, in particular their role in improving the quality of a country’s health system;
- The principle of equity and equal access of all citizens to health care in general and to essential drugs in particular.

The preamble then describes the foundations and principles of the NDP. It recalls political and organizational dispositions that are already taken to implement these principles in the health sector in general and in the pharmaceutical sector in particular, such as:

- Country’s adherence to the 1978 Alma-Ata Declaration on the primary health care strategy;
- Country’s adherence to the Lusaka Declaration on the 3-phase scenario for the organization of the national health system;
- Country’s adherence to the Bamako Initiative.

The preamble can indicate the place of the NDP within the context of NHP and relevant reforms undertaken under the structural adjustment programme, in particular the health, social and economic aspects of the structural adjustment programme.
2.5.3.4 General orientation of the National Drug Policy

This chapter presents the general guidelines concerning the development of the national pharmaceutical sector. This global orientation is the knot that holds together all the objectives, all the strategies and all the country’s plans for the pharmaceutical sector.

2.5.3.5 Objectives of a National Drug Policy

The objectives related to different components of the national pharmaceutical sector are defined. These objectives derive from priority problems of the drug sector identified during the situation analysis. The targets for a certain period can also be defined.

2.5.3.6 Institutional and operational strategies

The strategies required to reach the NDP objectives are developed. For each objective, external and internal constraints, which could hinder its implementation, should be identified, and appropriate strategies defined.

2.5.3.7 Proposed accompanying measures

In this part of the document, important accompanying measures to the formulated policy are identified to assist the government to implement the strategies for improving the national pharmaceutical sector as indicated in the preamble and the general orientation of the NDP.

2.5.4 Phase 4 - Wide circulation of the draft document

The working group submits the draft NDP document to external experts and stakeholders for comments. Results of these consultations will help to improve the content of the draft NDP document.

2.5.5 Phase 5 - Consensus workshop on National Drug Policy

The working group organizes a national workshop of 3 to 5 days to develop the NDP on the basis of the draft NDP document. All parties concerned with the pharmaceutical sector, i.e. other ministries, professional groups, universities,
nongovernmental organizations (NGOs), and bilateral and multilateral cooperation agencies should be involved and invited to this workshop. The participation of all parties and their adherence to the goals, objectives and strategies of the NDP will ensure its effective implementation.

The draft document should be sent to the participants at least two weeks before the workshop in order to obtain full participation and contribution from all of them.

The end result of the workshop should be the review, amendment and adoption of the general orientations, objectives and strategies for each component of the draft NDP document prepared by the working group.

2.5.6 Phase 6 - Finalization of the National Drug Policy document

The working group, joined by some participants, will finalize the draft NDP document on the basis of the recommendations of the national NDP workshop. After it is finalized, the NDP document is transmitted to the MOH who will submit it to the Cabinet for government approval and adoption.

2.5.7 Phase 7 - Approval of the National Drug Policy document

The NDP document spells out the intentions of the government. It is prepared under the responsibility of the MOH. However, it is a government document and has to be submitted to the government for approval and adoption. It is only after being approved and adopted by the government that the document becomes the official NDP.

2.5.8 Phase 8 - Publication of the official National Drug Policy document

The official NDP document should be printed in sufficient number of copies for distribution to all concerned and interested parties.

2.5.9 Phase 9 - Public launching of the National Drug Policy

The NDP should be officially launched for advocacy purposes. The NDP document is then widely distributed and promoted in various seminars. It will only become operational when implemented.
2.5.10 Phase 10 - Planning for the implementation of the National Drug Policy

This is a transitional phase between the formulation of a NDP and its implementation. This implementation should be planned, i.e. to prepare a certain number of prerequisites in order to implement the NDP. These prerequisites include the following: the institutional framework required for the implementation of the NDP, the necessary resources, and a monitoring and evaluation system.

2.5.10.1 Prerequisites for implementing a National Drug Policy

The following prerequisites can facilitate the implementation of a NDP:

- An operational administrative structure (e.g. pharmacy department) which is responsible for the implementation of the NDP;

- Creation by ministerial order of a multidisciplinary and multisectoral team to monitor the implementation of the NDP. It gives its views on drug problems and issues, and monitors and evaluates the effects of the NDP on the national drug sector. The team should be provided with financial resources to carry out its mission;

- Distribution and promotion of the NDP to all ministries, parliament, NGOs, pharmaceutical companies, and national and international organizations involved in the development of the health sector;

- Preparation of a National Drug Policy Implementation Plan (NDPIP) which determines inter alia activities to be undertaken to improve the drug situation of the country. The NDPIP is generally prepared for a period of five years;

- Prepare an action plan for a period of 1, 2 or 3 years.

The result from the formulation and implementation of a NDP is not only the production of a document but also the exchange of ideas between various partners who may contribute to positive changes in the national pharmaceutical sector.

2.5.10.2 Implementation of the National Drug Policy

Once formulated, a NDP is implemented through a plan of action. The process of development of a NDPIP is explained in a separate guide.
3. **SUMMARY**

The table below summarizes the process for formulating a NDP as discussed in the previous pages.

**TABLE 1. PROCESS FOR FORMULATING A NATIONAL DRUG POLICY**

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<td>- Examine the crisis situation; - Allocate resources</td>
<td>- Decision to formulate - Constitution of a working group</td>
</tr>
<tr>
<td>2. Situation analysis of pharmaceutical sector</td>
<td>- MOH - Working group</td>
<td>- Data collection - Data analysis</td>
<td>Pharmaceutical sector the study.</td>
</tr>
<tr>
<td>3. Formulation of a draft NDP</td>
<td>- Working group - Experts</td>
<td>- Writing the draft NDP - Review the draft NDP by experts of each component</td>
<td>Draft NDP document</td>
</tr>
<tr>
<td>4. Wide circulation of draft document</td>
<td>- Working group</td>
<td>- Distribution to external experts and all stakeholders - collection and incorporation of comments</td>
<td>Improved draft NDP document</td>
</tr>
<tr>
<td>5. Consensus workshop on NDP</td>
<td>- MOH - Working group - Concerned parties</td>
<td>- Review the draft NDP document by the national workshop - Adoption of the draft NDP by the national workshop</td>
<td>Draft NDP adopted by the national workshop</td>
</tr>
<tr>
<td>6. Finalization of NDP document</td>
<td>Working group</td>
<td>Incorporation of amendments</td>
<td>Final NDP document</td>
</tr>
<tr>
<td>7. Approval of NDP document</td>
<td>Government</td>
<td>- Review the final NDP document by the Government</td>
<td>Official NDP</td>
</tr>
<tr>
<td>9. Launching, distribution and promotion of NDP</td>
<td>- Working group - MOH</td>
<td>- Distribution of copies to representatives of concerned parties - Sale in bookshops - Conference for promotion - Radio, TV transmission</td>
<td>- Concerned parties informed - General public sensitized</td>
</tr>
</tbody>
</table>
GUIDE II
IMPLEMENTATION OF A NATIONAL DRUG POLICY
1. **INTRODUCTION TO GUIDE II**

The formulation, adoption and promotion of a NDP are not enough to ensure its implementation. In fact, the formulation and adoption of a NDP constitute the beginning of a long process. Implementing a NDP means translating it into specific operational activities. The implementation of a NDP requires a National Drug Policy Implementation Plan (NDPIP) with a Priority Action Plan (PAP). The NDPIP is sometimes referred to as Pharmaceutical Master Plan.

In this guide, a NDPIP is considered as part of the planning process. To implement a NDPIP, it is necessary to prepare a plan of priority activities, which will lead to the goals of the NDPIP. This is done by developing a PAP. The present guide describes procedures to formulate a NDPIP and a PAP.

2. **THE NATIONAL DRUG POLICY IMPLEMENTATION PLAN**

2.1 *What is a National Drug Policy Implementation Plan?*

A NDPIP is an overall plan which contains a detailed analysis of the pharmaceutical sector problems, the objectives, strategies and activities likely to solve the identified problems during a given period. The NDPIP is developed on the basis of the NDP document.

The following table helps to understand the hierarchy of objectives in the planning process.

**TABLE 2. HIERARCHY OF OBJECTIVES IN THE PLANNING PROCESS**

<table>
<thead>
<tr>
<th>Scope of the objective</th>
<th>Formal action</th>
<th>Type of Planning process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mission/Aims</td>
<td>National Drug Policy</td>
<td>Normative/Strategic</td>
</tr>
<tr>
<td>General Objectives</td>
<td>National Drug Policy</td>
<td>Tactical</td>
</tr>
<tr>
<td></td>
<td>Implementation Plan / National Programme</td>
<td></td>
</tr>
<tr>
<td>Specific/General Operations</td>
<td>Project</td>
<td>Operational</td>
</tr>
<tr>
<td>Usual operations</td>
<td>Priority Action Plan</td>
<td>Operational</td>
</tr>
</tbody>
</table>

Formulation and implementation of a national drug policy
2.2 Why formulate a National Drug Policy Implementation Plan?

A NDPIP is formulated in order to put a NDP into action and to know where one is going (general objectives), how one will get there (strategies), when one will get there. The NDPIP leads to better planning and to better programming of activities to be implemented in relation to the NDP in order to improve the pharmaceutical situation of a country. Another answer to the question “why prepare a NDPIP?” can also be found in the nature of the document as a tool for the coordination of different inputs in the pharmaceutical sector. Since many partners are involved in the drug sector, and it is necessary to orient interventions, the national drug policy states principles and the NDPIP puts these principles into action.

The NDPIP document is an important instrument for resource mobilization when it is used to negotiate with donor agencies for financing of the planned activities. Some agencies require NDP and NDPIP documents in order to discuss the possibility of funding the pharmaceutical sector. Each country should therefore have them.

Finally, implementation of activities in the pharmaceutical sector requires that objectives, strategies, actions and procedures be communicated to members of the team. A NDPIP document is therefore a communication document for all those in the national pharmaceutical sector. It is a useful document to strengthen the management, the decision-making and the negotiation capacity of the ministry of health in its efforts to improve the accessibility and rational use of drugs in the country.

2.3 What is a Priority Action Plan?

A priority action plan (PAP) is a plan containing priority activities to be implemented within a short or medium period in order to reach the objectives of a NDPIP. It is an operational plan that groups together activities which contribute to solving one or several problems identified in the NDPIP.

2.4 Why have a Priority Action Plan?

A NDPIP contains goals, objectives and strategies to improve the functioning of the pharmaceutical sector of a country. These objectives and strategies must be translated into operational objectives and specific activities. A PAP is prepared on this basis and it contains specific and operational objectives to achieve in a short or medium term. A PAP is a manager’s document while a NDPIP is a decision-maker’s document.
3. METHODOLOGY FOR FORMULATING A NDPIP AND A PAP

3.1 Initiative for the formulation of a NDPIP/PAP

Based on the NDP document, the MOH has to take the initiative of translating the policy into action. Elements given in this guide are enough to allow MOH experts to prepare the NDPIP document without external consultation/assistance. However, the MOH may request technical support to assist the national experts. Whether it is prepared by national or external assistance, the MOH will have to supply financial resources to the working group in charge of developing the NDPIP/PAP.

3.2 Formulation of a draft NDPIP

The formulation of a NDPIP comprises 3 main steps.

3.2.1 Step 1 - Constitution of a working group

The Minister of Health designates a working group composed of 5 or 7 experts to develop the NDPIP. The Chairman of the group should have proven authority and competence in the Ministry. It is better that the group be composed of experts who took part in the formulation of the NDP and also specialists in planning and financial management of the MOH or other ministries.

The Minister of Health defines the terms of reference of the working group and specifies the duration of its mission. The Minister also provides the working group with all the material and financial resources required to carry out the activity.

3.2.2 Step 2 - Preparation of the draft NDPIP

On the basis of the NDP document and other documents used for the country situation analysis, the working group prepares a draft NDPIP.

The priority problems identified in the NDPIP are detailed, updated and grouped in the following activity areas:
• Drug legislation and regulation;
• Drug regulatory authority;
• Selection of drugs and pharmaceutical products;
• Drugs supply;
• Cost of drugs and pricing policy;
• Pharmaceutical quality assurance;
• Rational drug use;
• Mode and source of drug financing and financial resources allocated to drugs;
• Human resources development in the pharmaceutical sector;
• Drug information and promotion;
• Research and development;
• Technical cooperation among countries;
• Traditional medicine.

The draft NDPIP document can be prepared following the outline proposed below.

3.2.2.1 Introduction to the NDPIP

This part introduces the NDPIP in relation to the NDP. The contents of the NDPIP document are also summarized to give an idea of what is in the NDPIP.
3.2.2.2 Situation Analysis

This part contains a detailed analysis of the existing situation in the national pharmaceutical sector. It analyses in detail each priority problem identified in the NDP document. This analysis, which establishes the cause-effect relationship, will serve as the basis and even justify the priority actions that will be undertaken. It brings out in detail the priority problems identified in the supply and logistics system, rational drug use, quality assurance, coordination, and economic and financial management.

3.2.2.3 Objectives

The objectives that the NDPIP intends to attain are defined based on the global objectives of the NDP. For each objective, one or several results to be attained are determined. Each objective and each result should have an indicator to allow monitoring and evaluation of its realization.

One way of defining the objectives is by using the tree of objectives as in Annex 1.

3.2.2.4 Strategies

This part presents strategies to be implemented in order to reach the objectives of the NDPIP. More details on how to identify those strategies are found in Annex 2 of this guide. These strategies should be more specific than the ones formulated in the NDP document.

3.2.2.5 Activities

This section identifies activities to be undertaken in order to obtain results and reach the objectives identified in the NDP and NDPIP.
3.2.2.6 Necessary resources

In this part, human, financial and material resources necessary for the execution of activities are identified. This is the beginning of the procedure for preparing a budget for the NDPIP.

3.2.2.7 Timetable

This part contains the duration of each activity in the plan. This timetable can be in the form of a Gantt table.

3.2.2.8 Budget for NDPIP

The budget for the NDPIP is based on resources identified in section 3.2.2.6. This budget includes investment costs and recurrent costs.

3.2.2.9 Expected effects of NDPIP

In this section, the expected effects of a NDPIP on the pharmaceutical sector are set out. There may be expected changes in supply and logistics, rational drug use, quality assurance, drug financing aspects and in the management of the whole sector.

All these elements are summarized in Table 3.
TABLE 3: NDPIP MODEL

<table>
<thead>
<tr>
<th>Component</th>
<th>Problems</th>
<th>Objectives</th>
<th>Strategies</th>
<th>Activities</th>
<th>Resources</th>
<th>Timetable</th>
<th>Budget</th>
<th>Sources</th>
</tr>
</thead>
</table>
3.2.3 Step 3: Preparation of the Priority Action Plan

From the NDPIP, avoiding duplication of identical activities, priority problems are identified by regrouping them in order to have a priority action plan whose elements lead to the resolution of identified problems. The PAP contains priority programmes to be implemented within one, two or three years. The structure of PAP is the same as that of the NDPIP, but it has a specific timetable and denotes individuals responsible for implementation. For example, activities for training can constitute a training programme; activities for information dissemination can constitute an information, education and communication (IEC) programme. The development of a PAP is presented in Table 4.

3.3 Presentation of NDPIP and PAP to all stakeholders

3.3.1 Exchange of ideas between agencies involved in the national drug sector

The working group distributes the draft NDPIP and PAP documents to all seminar participants and to representatives of various institutions (ministries, professional organizations, pharmaceutical enterprises, universities, NGOs, bilateral and multilateral cooperation agencies, etc.). The working group collects written comments, and those made during specific interviews. It is necessary to give time to all agencies involved in the national pharmaceutical sector for useful improvements to the document and exchange of ideas.

3.3.2 Holding a national seminar for the presentation of the NDPIP and PAP

The working group organizes a national seminar that brings together experts and representatives of all parties concerned to present the NDPIP and PAP. This seminar is intended for information, advocacy and resource mobilization.

3.3.3 Publication and wide distribution of NDPIP and PAP

Adopted documents are printed and widely distributed.
TABLE 4: PAP MODEL

<table>
<thead>
<tr>
<th>Components</th>
<th>Activities</th>
<th>Monitoring Indicators</th>
<th>Sources of funds</th>
<th>Timetable Responsible</th>
<th>Duration</th>
</tr>
</thead>
</table>

Formulation and implementation of a national drug policy
4. SUMMARY

The table below summarizes the process of developing a NDPIP, responsible persons for each step and the expected results.

**TABLE 6. STEPS FOR THE FORMULATION OF A NDPIP/PAP**

<table>
<thead>
<tr>
<th>Steps</th>
<th>Responsible</th>
<th>Actions</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Constitution of a MOH group</td>
<td></td>
<td>- Examine recommendations from NDP adoption and approval seminar</td>
<td>- Decision to formulate a NDPIP and PAP</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Designation of a focal point</td>
</tr>
<tr>
<td>2. Preparation of the draft NDPIP</td>
<td>MOH Focal Point</td>
<td>- Designation of a focal point</td>
<td>Plan of work</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Necessary resources made available</td>
<td></td>
</tr>
<tr>
<td>3. Formulation of the draft NDPIP</td>
<td>Focal Point</td>
<td>- Reactualize identified problems in NDP</td>
<td>Draft NDPIP document</td>
</tr>
<tr>
<td></td>
<td>Working group</td>
<td>- Produce a working document following the described methodology</td>
<td></td>
</tr>
<tr>
<td>4. Formulation of the draft PAP</td>
<td>Focal Point</td>
<td>- Identify priority programmes</td>
<td>Draft PAP document</td>
</tr>
<tr>
<td></td>
<td>Working group</td>
<td>- Produce a working document following the described methodology</td>
<td></td>
</tr>
<tr>
<td>5. Workshop for the formulation of the draft NDPIP &amp; PAP documents</td>
<td>Working group extended to experts</td>
<td>- Hold a workshop to examine, improve &amp; complete the draft documents</td>
<td>Draft NDPIP &amp; PAP documents</td>
</tr>
<tr>
<td>6. Organization of a multisectoral seminar for the presentation of NDPIP and PAP</td>
<td>MOH Working group</td>
<td>- Hold a seminar for 2-3 days for the adoption of NDPIP and PAP</td>
<td>Final NDPIP &amp; PAP documents</td>
</tr>
<tr>
<td>7. Publication of NDPIP and PAP</td>
<td>MOH Focal Point</td>
<td>- Edit</td>
<td>Sufficient copies of NDPIP &amp; PAP documents</td>
</tr>
</tbody>
</table>

PAP : Priority Action Plan  
NDPIP : National Drug Policy Implementation Plan  
NDP : National Drug Policy
5. OPERATIONALIZATION OF A NDPIP

As indicated above, a NDPIP is operationalized through the formulation and execution of a PAP. The effective implementation of a PAP assumes the existence of an operational plan of activities, required human resources and a Directorate of Pharmaceutical Services.

Operationalization of the NDPIP requires a management team and necessary tools for the implementation of the PAP. This involves 5 important steps:

- Step 1: presentation of the PAP;
- Step 2: the timetable of activities;
- Step 3: setting up of an organizational environment;
- Step 4: mobilization of resources;
- Step 5: setting up a system for monitoring and evaluation of the NDPIP and PAP.

A short description of each step is given below.

5.1 Step 1: Presentation of the PAP

The nature, objectives, strategies, activities and organization of the PAP implementation will be explained to different interested parties. This is a step to confirm the commitment of the different interested parties for the implementation of the PAP.

5.2 Step 2: The timetable of activities

There can be an important time gap between the formulation and the implementation of the NDPIP. This gap might outdated the original planned timetable. In this step, the initial timetable is reviewed in order to set up a more realistic plan of activities that will include resources.
5.3 Step 3: Setting up of an organizational environment

The success of a PAP does not only depend on its technical merits, but also on the efficiency of the Directorate of Pharmacy in charge of its implementation. However, the MOH may decide to give the responsibility to independent bodies for the implementation of certain components of the NDP (e.g. DRA). In this step, the responsibilities and administrative procedures are clarified. There is a need to clarify what each one’s job will be, where, when, how and why. If there are pre-requisites for implementation, they will be examined in this step. If there are administrative and regulatory evaluations concerning the organization and functioning procedures that are to be promulgated or cancelled, this will be done in this step.

5.4 Step 4: Mobilization of resources

Based on an estimate of the budget for the NDPIP and PAP, necessary resources will be mobilized and made available for the implementation of planned activities through constant contact with donors and interested partners. Procedures for the management of mobilized resources or those that will be made available will also be formulated. Appropriate procedures for control and transparency in the management of resources will be set up.

5.5 Step 5: Setting up a system of monitoring and evaluation for the NDPIP and PAP

In this step, a monitoring and evaluation system for the activities, the results and achievement of the objectives of the NDPIP and PAP is developed and implemented. This system is useful to assist sound decision-making on drug supplies and logistics, rational drug use, management, and financial and economic aspects of the NDPIP and PAP.
6. CONCLUSION

The formulation of a NDPIP and a PAP is based on the following steps:

- Identification and nomination of a motivated MOH pharmacist to a high level of responsibility; he/she is the focal point and must count on a multidisciplinary team from both the public and private sectors. This team should be familiar with the major problems encountered in public health.

- Good preparation and organization of workshops to present the NDPIP/PAP documents to stakeholders.

- Involvement of all stakeholders: e.g. political authorities, managers in ministries, partners in the health sector, etc.

- Technical and financial support from various partners.

The result of this process does not rest only with the production of a planning document but also creates an opportunity for exchange among partners in the pharmaceutical sector.
GUIDE III

INDICATORS FOR MONITORING AND EVALUATION OF NATIONAL DRUG POLICIES
1. **INTRODUCTION**

During the implementation of the NDP, it is important to monitor the progress being made and to evaluate the results achieved in relation to the 3 major NDP objectives: to increase access to essential drugs; to improve the quality of drugs; and to promote their rational use. This part of the document will discuss the concept of monitoring and evaluation and will present indicators that the African Region may use for this purpose to monitor the progress made in the African pharmaceutical situation.

Monitoring and evaluation are two complementary but distinct parts of the management cycle. Monitoring refers to the continuous review of the degree to which the activities are carried out and planned targets are met. Evaluation refers to assessing as objectively as possible the degree to which the goals and objectives are fulfilled. WHO has published a manual, which provides the methodology for monitoring NDPs with a list of 129 indicators. The participants of the NDP workshops held in Harare, November 1998, and in Douala, May 1999, selected some of these indicators as the most useful and these are listed below.

The indicators include structural, process and outcome indicators.

1.1 **Structural indicators**

Structural indicators (ST) check if the structures required to implement the NDP components exist. These are “Yes”/“No” questions. The existence of the structure does not necessarily imply that the structure is operational. The performance of the structures is assessed with process indicators.

1.2 **Process indicators**

Process indicators (PR) also assess the progress being made over time towards specific targets defined at national level. A knowledgeable informant at central level can gather information for core structural and process indicators. Member States can easily complete or updated them periodically as necessary.

1.3 **Outcome indicators**

Outcome indicators (OT) measure the degree of the attainment of the NDP objectives of improved access, drug quality, and rational drug use. Access is measured in terms of the availability (geographical access) and the affordability (financial access) of essential
drugs. Access can more objectively be assessed by the proportion of people who have had their prescriptions completely filled. This could be measured through a household survey during which people are asked if their most recent prescription was completely filled: if not, to provide the reason (lack of drugs or lack of money). As household survey may be very expensive, a proxy method suggested in this document is to conduct an exit interview at the health facility and public/private retail outlets using the same questions. The limitation of both methods is that they miss people who could not go to health facilities due to several reasons, e.g. lack of money for drugs, lack of money for transportation, lack of health facility in the community and lack of communication infrastructure. Quality of drugs is measured by assessing the results of quality control tests and the existence of expired drugs on the shelves. Finally, rational use is measured by examining the patterns of drug use and the effective use of STGs and EDLs.

Two types of survey will be required to measure the core outcome indicators. First, a survey in 20 random public health facilities is used to gather information about current availability of essential drugs, stockouts, affordability of treatments, drug quality and prescribing habits. At least 30 prescriptions per health facility have to be analysed for measuring the prescribing behaviours. A similar survey in central, regional and district drug stores examines all the above-mentioned characteristics, except prescribing habits. Finally, a survey in 20 private retail outlets assesses the current availability, affordability of treatments and the drug quality. For data to be collected accurately and reliably, attention must be paid to appropriate survey design, sampling and data gathering techniques. The methods for carrying out these surveys are described elsewhere, e.g. WHO indicators for monitoring national drug policies.

Data from all 46 AFRO Member States can be aggregated and compared to examine trends and to observe the effects of global forces that affect the pharmaceutical sector. Comparisons among countries can be particularly interesting and convincing for policymakers.
2. THE INDICATORS

2.1 National drug policy *(Interview MOH)*

**Structure indicators**

ST1: Is there a formal NDP document that covers the public and private sectors? 

- YES ☐  NO ☐

  If yes (check one and year written):

  - Draft, _____
  - Official, _____

ST2: Is there an official NDPIP document? 

- YES ☐  NO ☐

  If yes (tick one and year written):

  - Draft, _____
  - Official, _____

2.2 Legislation and regulation *(Interview Drug Regulatory Authority)*

**Structure indicators**

ST3: Is there a drug legislation? 

- YES ☐  NO ☐

    If yes, year of enactment:

ST4: Have regulations based on the current drug legislation been issued? 

- YES ☐  NO ☐

ST5: Is there a drug regulatory authority? 

- YES ☐  NO ☐

ST6: Does the drug regulatory authority do inspections of manufacturers/producers? 

- YES ☐  NO ☐

ST7: Does the drug regulatory authority do inspections of drug retail outlets/pharmacies? 

- YES ☐  NO ☐
ST8: Are pharmacists legally entitled to substitute generic drugs for brand name products?  
YES ☐ NO ☐

ST9: Do drug donations comply with the WHO drug donation guidelines?  
YES ☐ NO ☐

ST10: Are there formal procedures for registering drugs?  
YES ☐ NO ☐

ST11: Is there a drug registration committee?  
YES ☐ NO ☐

ST12: **Drug registration:**  

- *Is there a drug registration fee?*  
  - Registration fee for generic drugs (in US$)  
  - Registration fee for branded drugs (in US$)
  
- *What is the drug registration renewal period?*  
  - Renewal fee for generic drugs (in US$)  
  - Renewal fee for branded drugs (in US$)  

**Process indicators**

PR1: Number of **drug outlets** inspected, out of total number of drug outlets in the country.  

PR2: Number of drug outlets in violation, out of total number of drug outlets inspected.  

PR3: Number of **manufacturers** inspected, out of total number of manufacturers in the country.  

PR4: Number of manufacturers in violation, out of total number of manufacturers inspected.  

PR5: Number of **samples collected**, out of total number of samples planned.
PR6: Number of samples tested, out of total number of samples collected.

PR7: Number of advertisements in violation of regulations on the ethical promotion of drugs, out of total number of advertisements monitored.

PR8: Total number of drugs currently registered (dosage form & strength).

2.3 Drug Supply

2.3.1 Public sector procurement procedures (Interview Central Medical Stores (CMS))

Structure Indicators

ST13: Are drugs usually procured in the public sector through competitive tender? YES □  NO □

ST14: Are tenders done under international nonproprietary name (INN)? YES □  NO □

ST15: Is procurement limited to drugs on the national essential drugs list (EDL)? YES □  NO □

ST16: Is procurement based on a reliable quantification of drug needs? YES □  NO □

Process indicators

PR9: Value of drugs from the national essential drugs list (EDL) procured in the public sector, out of total value of drugs procured in the same sector.
PR10: Number of locally manufactured drugs sold in the country, which are on the national essential drugs list (EDL), out of total number of drugs from the national essential drugs list (EDL).

PR11: Value of drugs purchased through competitive tender, out of value of drugs purchased.

PR12: Value of drugs purchased from local manufacturers through competitive tender, out of value of drugs purchased through competitive tender.

PR13: Average lead-time for a sample of orders in the last year, out of average lead-time during the past three years.

PR14: Number of drugs/batches tested, out of number of drugs/batches procured.

PR15: Number of drugs/batches that failed quality control testing, out of number of drugs/batches tested.

2.3.2 Public sector distribution and logistics (Interview CMS)

Structure indicators

ST17: Do you have a Standard Operating Procedure manual for drug storage? YES □ NO □

ST18: Is there a regular drug distribution schedule YES □ NO □

If yes, what is the periodicity?
Process indicators

PR16: Do drug deliveries arrive on time in health facility surveyed? YES □ NO □
Average delay in the past twelve months: ________ days

PR17: Average stockout duration for key drugs in the central and/or regional stores in the last year. (compare with previous years if information is available), ________

PR18: Average stockout duration for key drugs in a sample of remote facilities in the last year. (compare with previous years if information is available), (*) ________

2.4 Quality Assurance (Interview Quality Control Laboratory and Drug Regulatory Authority)

Structure indicators

ST19: Where is drug testing done when requested by the regulatory authority?
In the country □ Outside the country □ Name(s) ____________
________________

Outcome indicators

OT1: Number of:
a- drugs that failed quality control testing, out of the total number of drugs surveyed(?). ________
b- batches that failed quality control testing, out of the total number of batches surveyed(?). ________
OT2: Number of:
  a- drugs beyond the expiry date, out of the total number of drugs surveyed(*).
  b- batches beyond the expiry date, out of the total number of drugs/batches surveyed(*).

(*) Indicator requiring survey

2.5 Financing and pricing policy (Interview MOH and Drug Regulatory Authority)

2.5.1 Drug allocation in the health budget/public sector financing policy

Structure indicators

ST20: Are there any financing systems in addition to the public drug budget that contribute to the provision of drugs in the public sector?  YES □  NO □

Process indicators

PR19: Value of international aid received for drugs, out of value of public drug budget.

PR20: Drug budget out of MOH budget.  ____%  ____ (year)

PR21: Public drug budget spent, out of public drug budget allocated.  ____%

2.5.2 Pricing policy

Structure indicators

ST21: Are drug prices regulated:
  - In the private sector?  YES □  NO □
  - In the public sector?  YES □  NO □

ST22: Is there a system for monitoring drug prices?
  - in the private sector  YES □  NO □
  - in the public sector  YES □  NO □
2.6 Rational Drug Use (Interview MOH)

**Structure indicators**

**ST24:** Is there a national essential drugs list (EDL)/formulary using INN officially adopted?
- YES ☐ NO ☐
- Date last edition
- Is it widely distributed?
  - YES ☐ NO ☐

**ST25:** Is there an official drug committee whose duties include updating the national essential drugs list (EDL)?
- YES ☐ NO ☐

**ST26:** Is there a national publication (formulary / bulletin / manual, etc.), providing objective information on drug use?
- YES ☐ NO ☐

**ST27:** Is there a national therapeutic guide with standardized treatments?
- YES ☐ NO ☐

**ST28:** Is the concept of essential drugs part of the curricula in the basic training of health personnel?
- YES ☐ NO ☐

**ST29:** Is there an official continuing education system on rational use of drugs for prescribers and dispensers?
- YES ☐ NO ☐
ST30: Is there a drug information/toxicology unit/centre? □ YES □ NO

ST31: Are there therapeutic committees in the major hospitals? □ YES □ NO

**Process indicators**

PR22: Number of prescribers having access to a (national) STG, out of total number of prescribers surveyed (*). □ □

PR23: Number of training sessions on drug use for prescribers in the last year in the past three years □ □

PR24: Number of issues of independent drug bulletins published last year □ □

**Outcome indicators**

OT3: Average number of drugs per prescription (*). □ □

OT4: Number of prescriptions with at least one injection, out of the total number of prescriptions surveyed (*). □ □

OT5: Number of children under five with diarrhoea receiving antidiarrhoeal drugs, out of the total number of children under five with diarrhoea surveyed (*). □ □

OT6: Number of drugs from the national essential drugs list, out of the 50 best selling drugs in the private sector (*). □ □
OT7: Number of drugs from the national essential drugs list (EDL) prescribed, out of total number of drugs prescribed (*).

OT8: Number of patients who understand how to take their medication out of the total number of patients surveyed? (exit interview)

2.7 Availability of Essential Drugs (Interview MOH)

Outcome indicators

OT9: Number of drugs from a list of key drugs available in a sample of remote health facilities, out of total number of drugs on the same list. (*)

OT10: What is the estimated population having regular access to essential drugs? (*)

OT11: Was your prescription completely filled? (Exit interview) (*)

YES □ NO □

If NO, tick reason:

□ Funds not available
□ Drug(s) not available

2.8 Affordability of Essential Drugs (Interview MOH)

Outcome indicators

OT12: Average retail price of standard treatment of malaria/pneumonia, out of the monthly official minimum wage

OT13 Average expenditure per prescription (US$)
DEFINITION OF TERMS

• **Bottleneck:** is an internal or external factor causing a delay in an activity or a process. Just like an obstacle, it can be eliminated by applying an appropriate strategy.

• **Budget:** estimated expenses and revenues of an enterprise during a given period.

• **Constraint:** a characteristic proper to the internal and/or external environment that can impede or block the realization of an objective, but that one cannot eliminate. A constraint, one must live with it.

• **Effect:** is an expected change at the end of an action.

• **Gantt Table:** a table that contains a plan of activities with a time period. It shows for each activity, the duration, when it begins and when it ends.

• **Indicator:** is a measure of a state or a phenomenon

• **Investment:** is an action to invest, in an enterprise, funds destined to acquire goods for multiple use and for which the duration of life is more than a year.

• **National Drug Policy Implementation Plan:** is an overall plan which contains a detailed analysis of the pharmaceutical sector, identifies the aims and general strategies and determines priority actions leading to the resolution of problems of the sector during a given period.

• **Objective** is the end result a programme, a project or an institution seeks to achieve.

• **Obstacle:** is a bottleneck from the internal and/or external environment, which can block the attainment of an objective or a result. It can be eliminated by an appropriate strategy.

• **Operational Plan:** is a document that determines in detail who is going to do what, when, where, with what resources and why. It is a managerial tool in the process of translating programmes and projects into activities to resolve one or several problems. It converts the specific objectives into operations.
- **Plan**: Document that contains a group of programmes/projects and strategies explicitly expressed in order to attain an objective or a group of objectives.

- **Policy**: Declaration of intent in which the Government commits itself, on the basis of a number of values and principles, to achieve a number of objectives to resolve specific problems of the sector by implementing appropriate strategies. Any policy should set the goals, objectives and strategies required to resolve the major problems identified in the sector.

- **Problem**: gap between the actual and the desired situation.

- **Programmes**: organized aggregate of activities of technically related activities directed towards the attainment of defined objectives.

- **Project**: a set of activities structured to generate products of particular significance to one or several programmes over a specific period of time, using various sources.

- **Recurrent costs**: are expenses which serve to maintain an investment.

- **Result**: the direct effect, consequence or outcome of the application of a product.

- **Standards**: values or norms towards which all actions converge. It is on the basis of standards or values that policies are formulated.

- **Strategy**: is an approach or a way to achieve an objective and to eliminate obstacles or to bypass constraints of the internal or external environment that may impede or block the achievement of a policy.

- **Strategic Plan**: is a plan that contains approaches and means that will be used to eliminate obstacles and bypass constraints in the process of achieving the objectives of an organization.

- **Tactic**: all the means deployed in order to obtain a result.

- **Tree of objectives**: is a technique used to identify the objectives of a plan, a programme or a project. It is based on the use of a vertical logic.

- **Vertical logic**: is a logic that consists of asking two questions in the process of identifying objectives. When one or more objectives are identified for a particular level, how to achieve them should be asked. In order to verify if the answer to "how" is logical, the question "why" attain the objective is also asked.
ANNEX 1: HOW TO DEFINE THE OBJECTIVES OF NDPIP AND PAP

To define the objectives of NDPIP, one can use the technique of the tree of objectives. A tree of objectives helps to identify and illustrate the goals to be reached.

What is a tree of objectives? It can be defined as a diagram that illustrates the structure of the objectives of a project as well as the relationship among them. It is an important tool for every project.

How is a tree of objectives built? The steps described below should be followed:

TABLE 6. STEPS TO FOLLOW WHEN BUILDING A TREE OF OBJECTIVES

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Formulation of a list of project objectives referring to selected priority problems</td>
<td>Identification of global objective = One that includes all the others</td>
<td>Extend the tree by creating a second level</td>
</tr>
<tr>
<td>6</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Verify if objectives of the lower level are measurable</td>
<td>Review the already built tree</td>
<td>Extend the tree by creating a third level</td>
</tr>
</tbody>
</table>
A short description of each step is given below.

**Step 1: Formulation of a list of project objectives**

The formulation of the list of objectives is preceded, as it has been previously said, by a definition of the priority problems. The question to which one should give an answer in this step is: why does one wish to undertake the NDPIP? The answer to this question is the list of objectives one wishes to attain. Note that each problem or group of problems, each cause or group of causes, each consequence or group of consequences can correspond to one or several objectives.

**Step 2: Identification of a global objective covering all the other objectives**

After having listed the objectives, an overall or general goal on which all the other goals will be linked is identified. This general objective is on the first or the highest level of the tree. All the other objectives identified in the first step are then placed above the overall goal, care being taken to avoid duplication. In identifying this general objective, the following question has to be asked: what is the objective that includes all the other objectives? The identified overall objective becomes the aim of the NDPIP.

**Step 3: Extend the tree by creating a second level**

The objectives placed above the overall goal are therefore on the first level of the tree. In the third step, the tree is extended by creating a second level of objectives. One chooses objectives of this second level from the list of those established in step 1 or one identifies new objectives. A line is drawn to link these objectives. From that moment, the question “how” will be asked when one climbs the tree and “why” when one comes down. “Vertical logic” is used.

**Step 4: Extend the tree by creating a third level**

A third level is created by choosing one of the objectives of the second level and identifying sub-objectives to be achieved. Step 3 is then repeated for all the other objectives.
Step 5: Review the already built tree

The tree is reviewed in order to determine if all objectives are included, if another level of objective is to be added, or if an objective of a given level helps to reach more than one objective of a higher level. If the tree is complete, one goes to the sixth step. Otherwise, one goes back to the fourth step.

Step 6: Check if lower level objectives are measurable

The objectives should be measurable. If not, the tree must be extended by creating a new branch by repeating step 4. The general rule is that one stops building the tree on the fifth level. When one looks at the tree of objectives that has been constructed, all the objectives are defined on the basis of the aim of the project. In the first level, there are general objectives, in the second level, intermediate objectives are found; in the third level are specific objectives; in the fourth level, one finds strategies; and most of the elements of the fifth level are activities to undertake.

As already mentioned, the logic used to build the tree is based on the questions “How?” and “Why?” When the tree is read from top to bottom, the answer is being given to the question: “How are we going to realize this objective?” When the tree is read from bottom to top, the answer is being given to the question “Why should we pursue this objective?”
ANNEX 2: HOW ARE NDPIP STRATEGIES IDENTIFIED?

1. What is a NDPIP strategy?

When talking about a policy or an objective for NDPIP, one should immediately think about the concept of strategy. What is a strategy? Why do we need to formulate one or several strategies? How do we formulate the strategy of a project?

The implementation of a NDPIP takes place in a country’s internal and external environment. This environment is complex, unstable and changes all the time. It contains constraints and obstacles that may impede the realization of the NDPIP objectives. Even if there are no obstacles, which would be unusual, one should determine how objectives would be attained. This is the importance of having one or more strategies. The principle here is the following: “It is useless to define objectives without defining ways to achieve them”.

What is a strategy? To understand what a strategy is, two concepts should be introduced: obstacles or bottlenecks and constraints.

The difference between an obstacle and a constraint is that an obstacle can be eliminated in various ways whereas a constraint is characteristic of the community or the environment and it cannot be eliminated in short or medium term. Constraints should be identified and appropriate strategies should be developed in such a way that the constraints are taken into account during the implementation of a NDPIP.

A strategy is a framework that will guide the choice of activities in a NDPIP. The strategy is elaborated to allow those who implement the NDPIP to face obstacles and constraints from the internal and external environment.

A strategy is therefore a choice of actions to carry out in the process of realization the objectives of a NDPIP.

In short, the word strategy has several possible meanings. In the context of the NDPIP, a strategy is an organizational or operational approach to reach an objective. One will find a wide range of strategies, from the more general to more detailed.
2. **How to identify NDPIP strategies**

It is important to explain further the terms, obstacles and constraints which should be taken into account when strategies are identified to reach a specific objective.

Obstacles may be defined as bottlenecks that may impede the realization of objectives but can be resolved by identified strategies. Constraints are characteristics of the environment. They cannot be changed. Strategies should be adjusted to them.

Strategies can be identified following the steps below which represent the strategic planning procedure.

**Step 1: Choose an objective to reach**

A strategy is always connected to an objective. The first step in the process of identifying strategies is therefore to identify or to choose the objective.

**Step 2: Identify bottlenecks**

For the objective chosen in step 1, identify bottlenecks that may impede the realization of the objective. Identify the causes of the bottlenecks.

**Step 3: Identify potential constraints**

Before choosing a strategy to remove an identified bottleneck, it is important to search for potential constraints, which may impede the removal of bottlenecks. If the constraints are so limiting that they might probably slow down the implementation of strategies, it is necessary to choose other strategies.

**Step 4: Select appropriate strategies for each bottleneck**

Since there can be several strategies to eliminate a bottleneck, the appropriate strategy (ies) should be selected. Some strategies will be of a technical nature and will imply the use of a given technology. It is therefore important to determine the technology of a project and how to choose the appropriate technology.
ANNEX 3: IDENTIFICATION OF NDPIP ACTIVITIES

The aim of this step is to determine the activities that will be implemented to reach the expected results of a NDPIP. These activities can be subdivided into tasks. Activities and tasks may be intellectual; that is to say they refer to the manipulation of concepts, abstract notions or to perception. They can also be physical; that is to say they resort to coordinated movements of the body or parts of the body.

Whether they use concepts or physical movements, activities and tasks often have an affective component (attitude). Activities and tasks that will be realized can be simple but are often complex. They are simple when they consist of elementary gestures. They are complex when they imply at the same time coordinated movements, manipulation of concepts or abstract notions and specific attitudes.

The steps presented below are necessary to identify activities of a NDPIP.

TABLE 7. STEPS FOR THE IDENTIFICATION OF ACTIVITIES

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Choose an objective</td>
<td>Choose the strategy to reach the objective</td>
<td>Identify activities for implementing the strategy</td>
<td>Indentify tasks to accomplish each activity</td>
<td>Identify the responsible(s) for each activity/task</td>
</tr>
</tbody>
</table>

One can also use a process that will identify activities, tasks and those responsible for these activities and/or tasks by integrating the result before the strategy as follows:

<table>
<thead>
<tr>
<th>Objectives</th>
<th>Results</th>
<th>Strategies</th>
<th>Activities</th>
<th>Tasks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Both processes lead to the identification of activities, tasks and responsible persons for the activities.
ANNEX 4: IDENTIFICATION OF HUMAN AND MATERIAL RESOURCES FOR THE NDPIP

In this section of the NDPIP the following questions have to be answered:

- What resources will be required in order to carry out the NDPIP activities?
- What is the nature of these resources: human/material/financial?
- Where will these resources come from? From the national budget? From outside sources or from community participation?
- How much will they cost, if they have to be bought?
- If human resources, should they be trained on how to use equipment and materials as well as their maintenance? If yes, how much will the training cost, who will run it, where and when will it be done?

To answer these questions, the following scheme allows us to draw up a table of resources before describing them in detail in the NDPIP document.

TABLE 8. HUMAN AND MATERIAL RESOURCES REQUIRED

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Identify the activity</td>
<td>Identify the resources</td>
<td>Describe the nature of the resources</td>
<td>Determine the quality</td>
<td>Determine the source</td>
<td>Determine the total cost</td>
<td>Comment</td>
</tr>
</tbody>
</table>
ANNEX 5: TIMETABLE OF ACTIVITIES FOR THE NDPIP

How to prepare a timetable of activities for the NDPIP?

In each NDPIP document, there should be a timetable, or a schedule of the main activities of the project.

An assessment of the duration of each main activity shall be done with reference to someone who knows the activity better if necessary. It will be determined when an activity will start and when it will end.

One of the simplest tools that will be used to develop an indicative timetable of activities is the Gantt Table or Table of bars.

Here is the process to follow in making the table.

**TABLE 9. GANTT TABLE**

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Prepare a list of activities</td>
<td>Estimate the duration of each activity (beginning &amp; ending date)</td>
<td>Put duration on the table by the use of bars</td>
</tr>
</tbody>
</table>

Each step is briefly described below.

**Step 1:**

Prepare a list of NDPIP activities following the order or the sequence in which they will be realized. The table of activities can also be used.

**Step 2:**

Estimate the duration of each activity, indicating when it will begin and when it will end. Take into account all the elements that would have an impact on the execution of activities to estimate its duration.

**Step 3:**

Put in the table, activities as indicated in step 1. Indicate with bars in the same table when the activities will start and when they will end.
ANNEX 6: BACKGROUND INFORMATION

Field tests have shown that the background information can be collected in a few days, if adequate access exists to key personnel in the health sector. Most of these indicators are provided in the annual reports of major international organizations (e.g. the International Monetary Fund, the United Nations Development Programme, the World Bank, etc…). However, in a few countries, some information, mainly on financial aspects, may be difficult to collect and not very reliable. It is then important to review each indicator, and to determine its usefulness in the national context and the level of «precision» which is needed.

COUNTRY INFORMATION

Population data

BG1: Total population
BG2: Average annual growth of the population
BG3: Percentage of the total population living in urban areas
BG4: Life expectancy (years)

Economic data

BG5: GNP per capita
BG6: Average annual rate of inflation
BG7: What is the official minimum wage (urban)?
BG8: What is the official minimum wage (rural)?

HEALTH INFORMATION

Health status data

BG9: Infant mortality rate (per 1,000 live births)
BG10: Maternal mortality rate (per 100,000 live births)
BG11: Top five causes and rate of infant morbidity
BG12: Top five causes and rate of infant mortality
BG13: Top five causes and rate of adult morbidity
BG14: Top five causes and rate of adult mortality
Health system data

BG15: Total number of prescribers
BG16: Total public health budget
BG17: Total value of international aid for the health sector
BG18: Total health expenditure (public + households + international aid)

DRUG SECTOR INFORMATION

Economic data

BG19: Total public drug expenditure
BG20: Total value of international aid for drugs (cash + kind)
BG21: Total drug expenditure (public + households + international aid)
BG22: Total value of local production (ex-factory price) sold in the country
BG23: Total value of drug imports (CIF)
BG24: Total value of drugs under generic name (CIF price for imported drugs and ex-factory price for locally produced drugs) sold in the country

Human resources

BG25: Total number of pharmacists
BG26: Total number of pharmacy technicians or other aides/assistants

Drug sector organization

BG27: Total number of drug manufacturing units in the country
BG28: Total number of wholesalers in the country
BG29: Total number of pharmacies and drug outlets in the public sector (including health facilities and hospitals that dispense drugs)
BG30: Total number of pharmacies and drug outlets in the private sector
BG31: Total number of private pharmacies and drug outlets in the three major urban areas
Number of drugs

BG32: Total number of registered drugs (in dosage forms and strengths)\(^4\)
BG33: Total number of drugs on the national essential drugs list (in INN)

(*) Indicator requiring survey

1 Public finance is understood as general government revenues and compulsory health insurance (sometimes known as social insurance) that is either publicly managed or heavily regulated by governments. Private finance includes out-of-pocket payments and voluntary health insurance.

2 From BG19 to BG24: when data do not distinguish between drugs and other supplies, try to estimate the percentage that corresponds to drugs and record this estimate.

3 If there is a sizeable illegal market, some realistic estimations of the share of this market in drug expenditures should be given.

4 In some countries the number of registered drugs is considerably higher than the number of drugs currently on the market. In such cases, countries are advised to add an indicator: "Number of drugs currently on the market".
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