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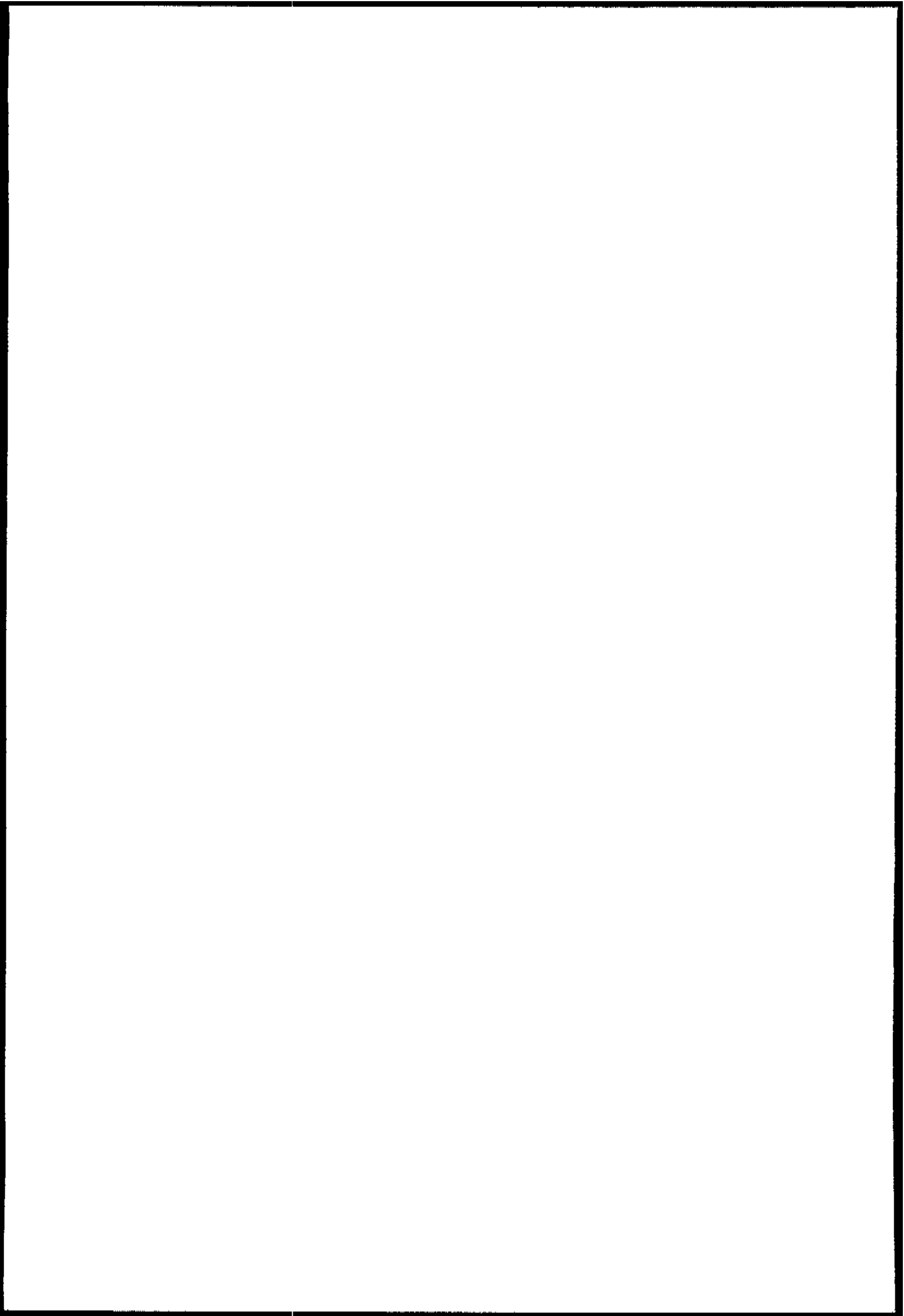
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Meeting of regional experts on the formulation and implementation of national drug policies and pharmaceutical master plans

Adapted from the original french version



Brazzaville, 26-30 April 1993
Meeting Report





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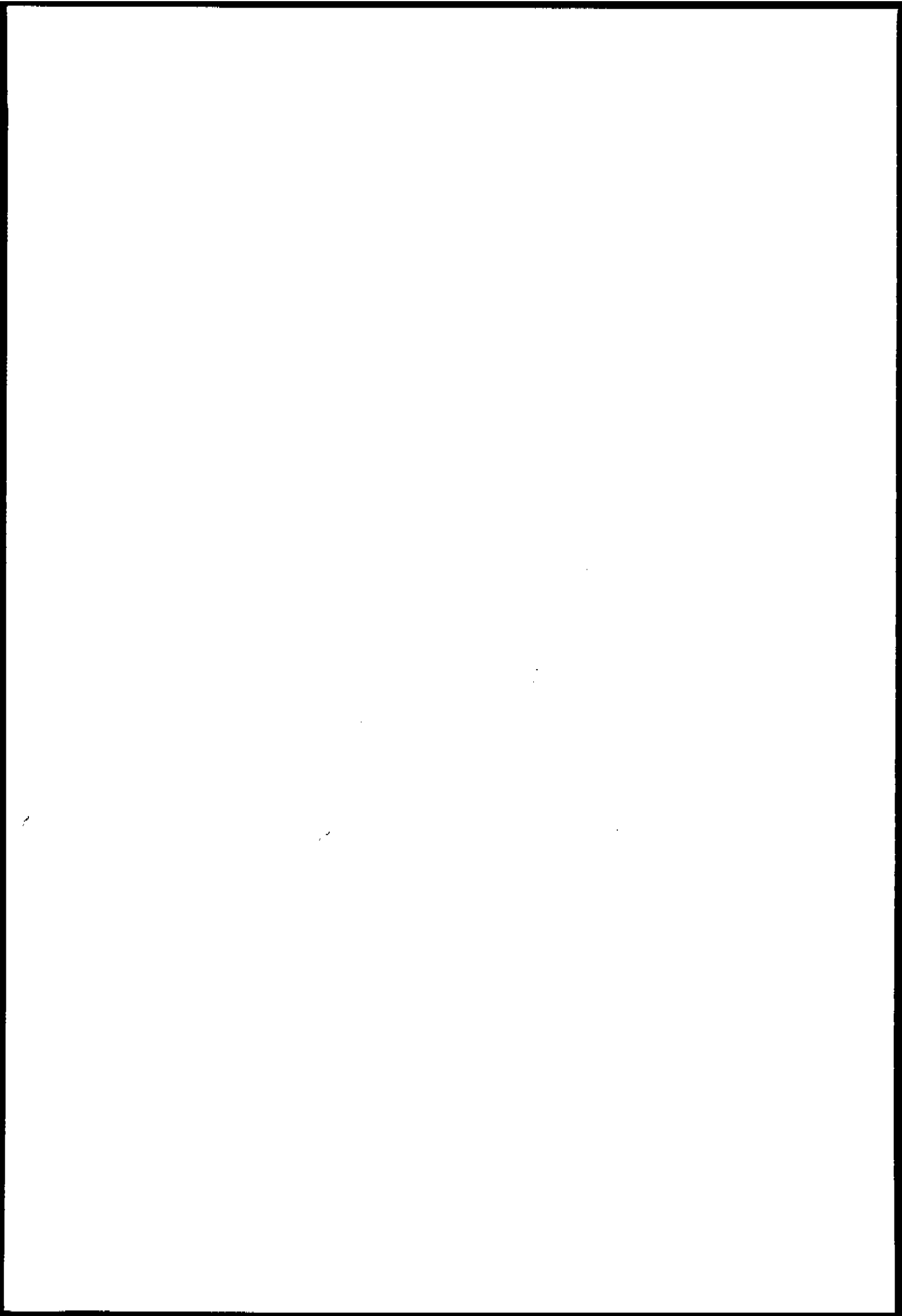
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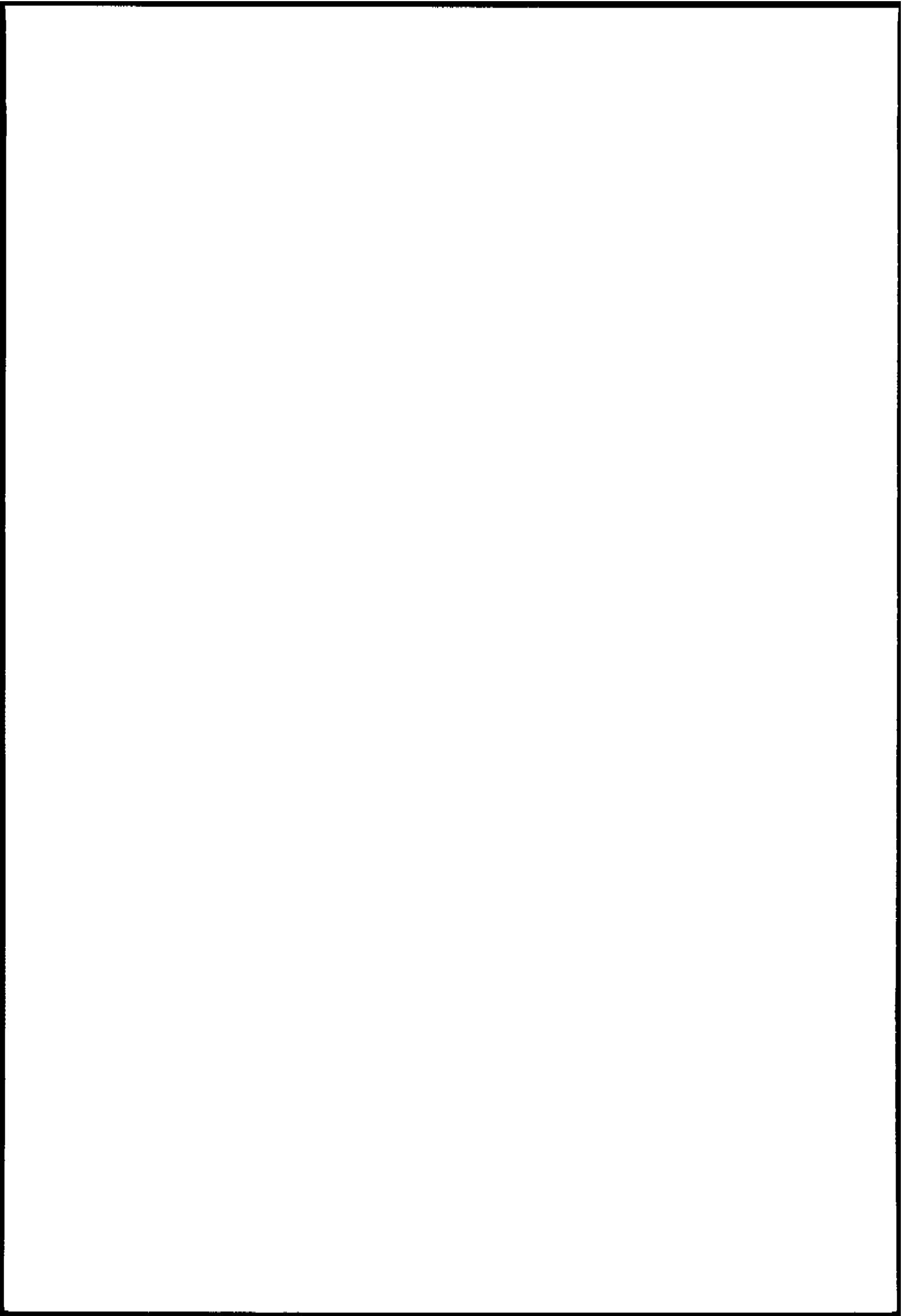
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Abbreviations

AFRO:	World Health Organization, Regional Office for Africa
CREDES:	Centre de Recherches et d'Etudes pour le Développement de la Santé
DANIDA:	Danish International Development Agency
DAP:	Action Programme on Essential Drugs
EDP:	Essential Drugs Programme
EDV:	Essential Drugs and Vaccines
KPI:	Keko Pharmaceutical Industry
MoH:	Ministry of Health
NAPCO:	National Pharmaceutical Corporation
NDP:	National Drug Policy
ODA:	Overseas Development Agency
TPI:	Tanzania Pharmaceutical Industry
UNICEF:	United Nations Children's Fund
WHO:	World Health Organization



I. Introduction

In 1986, the Thirty-ninth World Health Assembly invited the World Health Organization (WHO) to support governments in the formulation and implementation of national drug policies and essential drugs programmes. During an informal meeting on cooperation between the Action Programme on Essential Drugs (DAP) and French speaking countries in Africa, it was learnt that only 22 countries in the AFRO region have formulated drug policies and that only 7 (32%) of them are French-speaking.

Fifty percent of the world's inhabitants do not have access to the most needed essential drugs. The seventy-five percent of the world's population who live in developing countries consume less than 20% of the drugs on the world drug market which is estimated at US\$ 170 billion. The reasons for insufficient drug supply in developing countries are not only financial and budgetary constraints, but also the attitude of governments, prescribers, dispensers and the pharmaceutical industry. In order to coordinate activities carried out by different actors in the national pharmaceutical sector, each country needs to adopt a national drug policy (NDP) and a pharmaceutical master plan for its implementation.

The Action Programme on Essential Drugs has always stressed the importance of guidelines for the formulation of national drug policies. The Programme has carried out several activities in this respect. Some of these activities are for instance a meeting on "Drug Policy and Management", which took place in Geneva from 25-29 October 1982; the publication of documents entitled "The essential drugs concept and its implementation" (1985) and "Guidelines for developing national drug policies" (1988); the meeting of regional experts held in Brazzaville in November 1991 to prepare the Pharmaceutical Master Plan for the WHO Region for Africa.

It is in the same line of activities that DAP also organized a meeting of regional experts from 26-30 April 1993 in Brazzaville. The objectives of this meeting were twofold:

- to analyze the mechanisms for formulating and implementing national drug policies;
- to prepare operational guidelines for the formulation and the implementation of national drug policies and pharmaceutical master plans.

These guidelines are based on country experiences (Benin, Burundi, Guinea, Sudan, Tanzania, Yemen) and the review of various working documents such as the NDP of Liberia, Malawi, Nigeria, and Tanzania. These guidelines should be simple to understand and easy to use. Nationals will be trained on how to use them. The regional experts defined the NDP concepts and underlined the conditions and factors to be considered as well as the steps to be followed in the formulation and the implementation of coherent national drug policies.

These DAP initiatives are aimed at increasing the number of countries with national drug policies and corresponding master plans. In this manner, the Action Programme on Essential Drugs can achieve one of its major priority objectives: the development and implementation of coherent national drug policies aimed at improving the availability, accessibility and rational use of essential drugs.

II. Summary: Country Experiences with the Formulation and the Implementation of National Drug Policies

Benin:

During the past ten years health authorities have shown a keen interest in the formulation of a NDP even though the socio-economic environment has not been very favourable to this formulation. The formulation of a NDP became a condition for the World Bank's continued financial support to the country. Before the adoption of the final NDP document several meetings took place between professionals in the field and other interested parties.

Discussions from several meetings and workshops led to the preparation of a national pharmaceutical master plan and a priority action plan. More details on the processes followed in the formulation of the NDP are provided in annex 2, A.

Burundi:

A national drug policy document has not yet been adopted. However, an essential drugs programme has been developed with assistance from DAP and other partners.

In May 1990, a national meeting was organized with DAP support to formulate a NDP based on priority major problems identified in the national pharmaceutical sector. The Ministry of Health has not implemented all the recommendations of the meeting.

A national commission has been created by the Ministry of Health to formulate a comprehensive NDP following the recent escalation of drug prices in the country. More details on the processes followed in the formulation of the NDP are provided in annex 2, B.

Guinea:

A national drug policy has not yet been formulated. However, the national health conference held in 1984 defined a national health policy which included the objectives of a NDP.

With the support of WHO/DAP and other organizations, certain elements of the NDP have already been implemented: legislation, creation of a National Drug Commission, National Body of Pharmacy Inspectors, preparation of an essential drugs list and a national drug formulary.

In order to coordinate all efforts of various interested parties in the national pharmaceutical sector, the formulation of a NDP which outlines the governmental orientations in this field is in process. More details on the processes followed in the formulation of the NDP are provided in annex 2, C.

Sudan:

Sudan was marked by serious drug price problems which forced the government to adopt a health policy based on the principle of primary health care. The national meeting held in 1980 recommended that the Government adopt measures which would ensure the efficient use of available limited foreign exchange for the procurement of good quality essential drugs.

In February 1991, the Ministry of Health established a committee representing various

institutions to formulate the national drug policy which was then adopted by a ministerial decree. A five-member committee follows up its implementation. More details on the processes followed in the formulation and implementation of the NDP are provided in annex 2, D.

Tanzania:

Tanzania faced an economic crisis during the period of 1975-1985. The essential drugs were short nationwide. The government prepared the NDP in 1985, but due to administrative delays it was only in 1991 that the document received cabinet approval.

In view of these administrative delays, the government prepared the corresponding national pharmaceutical master plan before the NDP was approved. The national pharmaceutical master plan was completed in October 1991 and was approved in 1992. More details on the processes followed in the formulation of NDP and master plan are provided in annex 2, E.

Yemen:

Even though this country developed an essential drugs programme with assistance from WHO/DAP, it was only in 1992 that a NDP was prepared and adopted following pressure from the World Bank which made it a condition for its support to the pharmaceutical sector. More details on the processes followed in the NDP formulation are provided in annex 2, F.

Observations:

Discussions on the country experiences led to the following observations:

- Many countries have developed essential drugs programmes in order to solve specific problems.
- Others have prepared NDP or have made attempts to do so only as a reaction to internal crises related to drug availability and access.
- Others have done so due to pressure from donors.
- The rest of the countries have not prepared national drug policies because they received no guidance on how to do it.

The above observations justify the development of guidelines for the formulation and implementation of a NDP.

III. Development of Guidelines for the Formulation and Implementation of a National Drug Policy

After the group discussions and plenary sessions, the participants agreed upon the following contents of the NDP guidelines manual:

1. Introduction

The introduction should cover the following issues:

- Why DAP is developing guidelines for the formulation of a NDP?
- How many countries have formulated a NDP?
- What are the components of a NDP?
- Why a country should formulate a national drug policy?
- Who should use these guidelines?

2. Formulation methodology

The conditions necessary to formulate a NDP are the demonstration of political will and the budget to cover the costs of various activities related to the formulation of the NDP.

When these conditions are realized, the formulation of a NDP may proceed according to the following steps:

- Set up a multidisciplinary task force to formulate the NDP.
- Agree upon the structure and the components of the national drug policy.
- Carry out an economic, health and pharmaceutical situation analysis of the country by making visits and enquiries in ministries and other interested organizations, as well as by consulting available documents, etc.
- Adopt the NDP document after extensive consultations.

3. Implementation methodology

Following its development and its adoption, the NDP should be implemented. The following points are important for the effective implementation of the NDP:

- Nomination of a focal point to follow up on the implementation of the NDP.
- Creation of a national drug committee.
- Distribution and promotion of the NDP document.

- Formulation of a national pharmaceutical master plan.
- Formulation of a priority action plan.
- Follow up and evaluation.

IV. Development of Guidelines for the Formulation and Implementation of a National Pharmaceutical Master Plan and Priority Action Plan

The participants of the meeting discussed the pharmaceutical master plan for the AFRO region developed by a group of regional experts in November 1991. This master plan was developed by analyzing the drug situation in AFRO, identifying priority problems and preparing a plan to solve them. The plan has already been tested in Benin and has proved to be easy to use. After the group discussions and plenary sessions, the participants agreed upon the following contents of the pharmaceutical master plan guidelines manual:

1. Introduction

The introduction should emphasize the limited use of a NDP which is not translated into an operational pharmaceutical master plan. In addition, the introduction should cover the following issues:

- Why DAP is developing these guidelines?
- What does the pharmaceutical master plan concept contain?
- Who should use the guidelines?

2. Formulation methodology

The conditions necessary to formulate a pharmaceutical master plan are the demonstration of political will and the budget to cover the costs of various activities related to the formulation of the master plan.

When these conditions are realized, the formulation of a pharmaceutical master plan may proceed according to the following steps:

- Set up a multidisciplinary task force to formulate the plan.
- Agree upon the structure and the components of the pharmaceutical master plan (national drug policy elements to be considered).

3. Implementation

- Distribution of the national pharmaceutical master plan.
- Search for financial resources and other resources required to implement the master plan (donor meeting, funding request with project proposals, etc.)
- Preparation of short and medium term implementation plan
- Follow up and evaluation.

V. Conclusions and suggestions

After the five day meeting, it was clear that the formulation and the implementation of national drug policies and master plans constitute a real problem in Member States.

Based on country experiences on various ways used to solve problems met in their pharmaceutical sector, the participants made the following suggestions:

1. Ministry of Health authorities through their professional staff should take the necessary steps to start preparing their NDP and pharmaceutical master plans.
2. DAP should publish the documents resulting from this meeting and give technical and financial support for the implementation of country collaboration programmes, particularly activities leading to the formulation of national drug policies and master plans.
3. WHO will make available the NDP and master plan documents to the participating countries in their working language and encourage technical cooperation between countries.

Annex 1. List of Participants

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Annex 2. Country Experiences with the Formulation and the Implementation of National Drug Policies

A. Benin

Dr Adolphe Topanou

1. Formulation of the national drug policy

For the past ten years, drugs and the formulation of a national drug policy have been subjects of concern to national health authorities in the Republic of Benin.

The objectives of this policy were defined in relation with issues facing the health, political, economic and socio-cultural environment.

National health authorities and other interested parties were involved in the formulation of the NDP as they will also be involved in its implementation.

The formulation of the NDP went through the following stages:

- In 1982, the Ministry of Health organized a meeting with various interested parties. The goal was to define the major orientations of the NDP and harmonize efforts undertaken by various actors in the pharmaceutical sector.
- In 1986-1988, the Ministry of Health, the national pharmaceutical association, the national physicians association, partners in health development and other concerned ministries (finance, justice, commerce) prepared the first draft of the NDP. As a starting step for the formulation of the NDP, the pharmaceutical sector of Benin was analyzed and problems were identified. This work was slowed down by the political unrest at that time.
- In 1990, the formulation of a NDP was a condition for the World Bank financial assistance to the Benin health sector. The draft NDP mentioned above was then updated.
- In 1991, the draft NDP was finalized. It was then adopted during a national meeting in which participated the following institutions:
 - Ministry of Health
 - Ministry of Finance
 - Ministry of Commerce
 - Ministry of Planning
 - Ministry of Justice
 - Ministry of Home Affairs
 - National Pharmaceutical Association
 - National Physicians Association
 - Wholesalers
 - Pharmaceutical industries.

2. Formulation of the national pharmaceutical master plan and the pharmaceutical priority action plan for 1994-1996

The Republic of Benin adopted its NDP in 1991. The NDP objective is to ensure the availability and accessibility of good quality essential drugs and promote their rational use. The pharmaceutical master plan was developed to operationalize the NDP.

The master plan was formulated according to the following steps:

- Needs assessment by a DAP mission in February 1991.
- Nomination of a focal point in March 1991. The focal point and the director of pharmacy collected all the necessary information for formulating the master plan.
- Recruitment of a consultant by DAP in November 1992 to assist with the methodology for the formulation of the master plan.
- In December 1992, the consultant carried out a mission in Benin in order to:
 - form a working group of 8 national experts;
 - meet national health authorities: the focal point, the director of pharmacy and the minister of health;
 - meet various partners in the pharmaceutical sector: pharmacists, physicians, donors, ministries;
 - hold a three-day workshop to produce the draft master plan and the Priority Action Plan.
- The working group and the focal point continued working for three months in order to finalize the draft document and obtain comments from all involved parties.
- Return of consultant in March 1992 to hold a three-day seminar for adopting the master plan and the priority action plan for 1994-1996.

B. Burundi

Mr Severin Kambayeko

Burundi does not have a written comprehensive national drug policy. However, some elements of the policy such as the essential drugs list are implemented. After the Alma Ata conference in 1978, efforts were made to find solutions to existing drug problems. This was done in three phases:

1. Discussions between the Ministry of Public Health and other interested parties.

In 1980, the Ministry of Public Health requested assistance from WHO aimed at:

- Improving the drug supply system.
- Local production of IV fluids.
- Rational use of drugs.

The same year, WHO in collaboration with UNICEF and a group of pharmaceutical manufacturers (Interpharma), carried out a situation analysis which led to the implementation of an essential drugs programme with the following objectives:

- To improve the national pharmaceutical sector
- To provide logistical support to the Ministry of Health
- To quantify drug needs
- To organize drug management training seminars
- To select essential drugs according to the level of health care
- To improve drug storage facilities.

The project was evaluated in 1987. The evaluation report recommended that the project be continued.

2. Coordination meeting of different actors

In order to prevent any overlap of activities, the Ministry of Health, WHO, UNICEF and Interpharma developed a coordinated plan of action in March 1988.

3. National Drug Policy Meeting (2-5 May 1990)

After the project was jointly reviewed by different actors in July 1989, it was decided to organize a national meeting aimed at formulating a national drug policy. Various ministries were represented. The following components of a NDP were discussed:

- Rational drug use and selection
- Procurement and financing
- Distribution and dispensing
- Quality control and legislation
- Staff training and public education.

The objectives of the NDP were also defined as to ensure the availability of essential drugs, to increase drug accessibility, and to improve rational drug use.

The NDP meeting made the following recommendations:

Selection:

Urgent constitution of a national drug selection committee.

Procurement and quality assurance:

Rationalize Ministry of Health procedures which are a source of long drug delivery delays; start a national drug quality control laboratory.

Distribution:

Establish a central medical store.

Legislation:

Creation of a direction of pharmacy; revision of the existing drug legislation.

Drug accessibility:

Conduct studies on the harmonization of social security systems in order to increase the population's access to essential drugs; ensure the permanent availability of essential drugs and other vital medical products.

Rational Drug Use:

Develop and distribute therapeutic guides and treatment manuals; training of prescribers and public education on rational drug use.

Even though a lot has been achieved in Burundi, the NDP is still to be formulated and implemented. Following a recent escalation of drug prices and the need for appropriate financing mechanisms, the Ministry of Health is now in the process of redefining its national health policy as well as the general health development plan. The Ministry of Health has created a committee to prepare a draft NDP.

C. Guinea

Dr Mory Fofana

1. Introduction

The pharmaceutical sector was a state monopoly up to 1984. The second republic encouraged the creation of a private sector. As a result a large number of partners are working in the health/pharmaceutical sector in order to improve the health status of the population. WHO/DAP and other organizations have continuously supported the country in the implementation of several components of a NDP such as the selection of an essential drugs list, the national formulary, pharmacy inspection services, drug legislation, etc.

In order to coordinate the different interventions, it was necessary to formulate a NDP which outlined the government's orientations and preoccupations in this field.

2. Methodology

Since 1992, the formulation of a NDP has been part of the action plan of the direction of pharmacy. The MoH started the procedures for the formulation of a NDP by organizing a national workshop which had the following features:

- The participants were all from concerned departments/ministries and other external agencies involved in the pharmaceutical sector.
- The resource persons were consultants from DAP and CREDES.
- The duration of the workshop was two days.
- The topics discussed included:
 - problem identification: eight major problems were identified by the participants;
 - definition of priority objectives;
 - choice of strategies and activities to be carried out.
- Follow up strategy: a focal point was designated to follow up the implementation of the activities.

3. Constraints

Absence of a budget for the preparatory activities such as data collection, formulation and distribution of working documents, etc.

4. Recommendation

The most important recommendation was to consider the formulation itself as a problem. The MoH does not have the required budget and its personnel does not have the skills required to develop a NDP and a pharmaceutical master plan.

D. Sudan

Prof. A.H. Ibrahim

Before 1981, quality and efficacy were the only criteria for registering drugs imported into Sudan by the private sector. However high drug prices and lack of foreign exchange led to serious drug shortages both in the private and public sector.

A national meeting was held in November 1980 to discuss issues facing the development of the health sector in Sudan. The meeting recommended that the government adopt measures which would ensure the efficient use of available foreign exchange for the procurement of good quality essential drugs. These drugs should be in sufficient quantities and at the lowest possible cost in order to satisfy the needs of the majority of the population.

In February 1991, the Ministry of Health signed a decree establishing a 49 member committee composed of representatives from various health related institutions: ministries of health, planning, commerce, industry, and education, customs department, national bank, faculty of medicine, faculty of pharmacy, pharmacy and medical associations, labour unions, importers, association of retail pharmacists, etc.

The mission of the committee was to formulate a comprehensive national drug policy based on the essential drugs concept. The working document for the committee was prepared by five experts from the Ministry of Health. This document contained the recommendations of the national meeting and described for each NDP component the policy orientations and strategies. After three months, the committee produced a national drug policy document which was adopted by a ministerial decree. The Minister of Health formed a five-member committee to follow up on the implementation of the national drug policy.

E. Tanzania

Dr R. Mbwasi

1. Historical background

Tanzania has a centralized drug distribution system. Tanzania is still using the central medical stores established during the British colonial period to supply the public sector. The private sector has continued to obtain its supplies from private importers who are found mainly in the urban centres. Rural areas depended exclusively on the public sector for drug supplies.

When the socialist system was adopted, the government established a single supplier for the private sector called NAPCO or National Pharmaceutical Company. NAPCO had the monopoly for drug importation and distribution to retailers, distributors and hospitals.

In order to ensure the viability of the supply system, the government established two local manufacturing plants: TPI or Tanzania Pharmaceutical Industry and KPI or Keko Pharmaceutical Industry. This was done in order to ensure a certain level of self sufficiency in the procurement of the most essential drugs needed by the population in the country.

2. Economic problems

Between 1975 and 1985, Tanzania went through an economic crisis. The lack of financial resources in all sectors led to acute drug shortages and a break down of the health system. The health budget could hardly cover 50% of the country's health requirements. The central medical stores could no longer supply drugs to public health institutions and NAPCO was unable to supply the private sector.

3. Formulation of a national drug policy

- 3.1 The government showed its determination to formulate a NDP and requested the Ministry of Health to undertake the necessary steps for this purpose.
- 3.2 The Minister of Health named a task force composed of experts, Ministry of Health directors and other responsible officers. It was chaired by the director of clinical services.
- 3.3 The mandate of the task force was to prepare a working document based on various publications and views of responsible officers in the health sector. Some people were requested to prepare presentations on various NDP components.
- 3.4 The working document as well as other publications were sent to participants before the date of the workshop.
- 3.5 The first workshop was attended by professionals from various health sectors.

- 3.6 This first workshop lasted four days. Its recommendations were used by the task force in the preparation of the draft NDP.
- 3.7 Follow up workshop was planned for some months later in order to discuss the draft NDP, but could only be held much later.
- 3.8 The follow up workshop was thus held in 1988. The draft NDP was adopted and the working group finalized the document before presenting it to the Minister of Health for approval.
- 3.9 The government approved the NDP in November 1991.

4. Formulation of a master plan

- 4.1 Long delays had been experienced in the formulation of the NDP. In view of this, donors insisted that the master plan be prepared even before the adoption of the NDP.
- 4.2 In early 1991 the Minister of Health requested the task force to prepare the working document for the master plan during a national workshop.
- 4.3 The task force invited and interviewed various experts and resource persons. With financial assistance from DANIDA, six experts from the World Bank, WHO, UNICEF, DANIDA, and ODA joined the task force to help in the preparation of the working document for the national workshop. Various documents collected by the task force were used for this purpose.
- 4.4 The working document and other publications were sent to participants well in advance of the workshop.
- 4.5 The three-day workshop was attended by all participants at the NDP workshop as well as other experts in master plan development. It was chaired by the principal secretary in the Ministry of Health. The Prime Minister's office was also represented.
- 4.6 After the workshop the task force composed of national and international experts worked for three months to produce the draft master plan. During this period members of the task force continued to consult resource persons on specific problems.
- 4.7 Four weeks after the workshop, the draft master plan was sent to the Minister of Health for comments.
- 4.8 The Minister of Health collected comments from various heads of department and other responsible officers involved in the pharmaceutical sector.
- 4.9 After incorporating all the comments, the Minister of Health transmitted the draft master plan to the international experts of the task force for revision and preparation of the final version.
- 4.10 Six weeks later, the document was sent to the Minister of Health for approval.

- 4.1.1 Since the approval process was expected to take a long time, negotiations with the World Bank, WHO, DANIDA, etc. were engaged before formal approval. The Government approved the pharmaceutical master plan in 1992.

5. Conclusion

- 5.1 The Tanzanian experience shows that since the NDP approval process took a long time, it was decided to prepare the master plan before the approval.
- 5.2 In order to accelerate the formulation of the master plan, the second national meeting did not take place. Instead, the Minister of Health invited comments from some responsible officers before preparing the final version.
- 5.3 The priority action plan was not prepared by the workshop. This job was left to the planning team.

F. Yemen

Prof. A. H. Ibrahim

Since 1984, the drug programme in North and South Yemen has implemented certain elements of a national drug policy. However a national drug policy has not yet been formulated. The need for a NDP was felt in 1992 when a four-year (1993-1996) essential drugs programme was being developed with World Bank financial support.

A NDP workshop was held in December 1992 in Sanaa. There were 50 participants from the Ministry of Health, the university, local manufacturers and the private sector. The workshop was organized as follows:

1. Presentation of the elements of a NDP by a WHO consultant.
2. Presentation of the national health policy by the deputy secretary for planning.
3. The Pharmacy and Procurement Director presented the existing drug policy, strategies and plans being implemented.
4. For each element of the NDP, a resource person was assigned to present the current situation, problems, constraints and deficiencies, recommended policy, strategies and activities to correct the situation. Each presentation was followed by a general discussion.
5. On the third day, four working groups were assigned to work on the following NDP components:
 - drug control and legislation
 - drug supply and local production
 - education and training
 - information, drug promotion and health education.

Based on presentations by resource persons and the general discussions, the working groups prepared a document which contains the analysis of the current situation, the identification of existing problems and deficiencies, the definition of corrective measures to be included in the NDP.

6. The final work of the four groups was presented in plenary session by the group chairperson or rapporteur. The recommendations were adopted after discussions.
7. The chairpersons and rapporteurs of the four groups as well as four participants chosen by the workshop constituted a follow up committee for the implementation of the NDP. The committee was chaired by the Director of Pharmaceutical and Supply Services.
8. The draft NDP was finalized by this committee and the WHO consultant.

9. The draft NDP was presented to the Minister of Health for adoption following the existing procedures.

The procedures used in Yemen and Sudan were shortened to prevent long delays experienced in the development of national drug policies. However, these procedures involved representatives from various health related sectors including professional associations and the private sector.