

# TOOLS FOR INSTITUTIONALIZING TRADITIONAL MEDICINE IN HEALTH SYSTEMS IN THE WHO AFRICAN REGION

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**WORLD HEALTH ORGANIZATION**  
Regional Office for Africa  
Brazzaville



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Regional Office for Africa  
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## Foreword

Traditional medicine has been used by the majority of the population in the WHO African Region before the advent of modern medicine for the treatment of diseases. Indeed, the World Health Organization currently estimates that as much as 80% of the people living in the African Region use traditional medicine for their health care needs. Some of the modern medicines such as atropine, physostigmine and vincristine were isolated from medicinal plants. There is growing recognition of the important role that traditional medicine plays in overall health care delivery even in industrialized countries such as Australia, France, Germany and the United States of America. The important role played by traditional medicine and its practitioners in health care delivery was recognized by the Alma-Ata declaration in its Conference on Primary Health Care in 1978. The relevant recommendations of WHO governing bodies also address the strategic options that are expected to help achieve health for all. Regional partners and agencies of the United Nations—for example, African Union, World Bank, African Development Bank, International Union of Conservation of Nature, Food and Agriculture Organization, United Nations Industrial Development Organization, World Intellectual Property Organization—have also been stressing the importance of traditional medicine.

In the past few years, WHO and African leaders have shown a renewed political interest in the development of traditional medicine. WHO Regional Office for Africa developed a document entitled, *Promoting the role of traditional medicine in health systems: A strategy for the African Region* which was adopted by the fiftieth session of the WHO Regional Committee for Africa in Ouagadougou, Burkina Faso in 2000. WHO has also developed the global Traditional Medicine Strategy 2002-2005 which was adopted by the Fifty-sixth World Health Assembly in Geneva in 2003 through its resolution on traditional medicine (WHA56.13). In addition, WHO designated in 2002, the 31 August of every year as the African Traditional Medicine Day on request of Member States and the first was commemorated with the theme: *African Traditional Medicine: Our Culture, Our Future*. African Heads of State and Government declared, in Abuja in April 2001 and in Maputo in July 2003, that research on traditional medicines used for the treatment of malaria, HIV/AIDS and other infectious diseases, should be made a priority in the African continent; and in Lusaka in July 2001 that the period 2001-2010 should be the Decade for African Traditional Medicine. The plan of action for implementation of this period which received WHO support and was adopted by the Conference of Ministers of Health in Tripoli in April 2003 was endorsed by the African Summit of Heads of State and Government in Maputo in July 2003. These declarations and WHO resolutions by our leaders would further boost the development of traditional medicine to the benefit of the vast majority of Africans who use it for their health care needs.

These policy orientations notwithstanding, the reality is that few countries in the African Region have developed national policies, legal frameworks and codes of ethics and conduct for the practice of traditional medicine. Also notable is that some countries have set up associations of traditional health practitioners, established management bodies or national

expert committees responsible for coordinating traditional medicine activities. They have established national offices and programmes in the ministries of health, have developed laws for herbal medicines, including registration of traditional medicines, and developed programmes for training and continuing education of traditional health practitioners (THPs) including traditional birth attendants and for medical doctors, pharmacists and nurses. Furthermore, some countries have embarked upon the local production, on a pilot-scale, of various traditional medicines for the treatment of common ailments and priority diseases such as malaria, sickle-cell anaemia, HIV/AIDS, hypertension and diabetes. Some of these traditional medicines have been registered and included in national essential drug lists. Some research institutions are carrying out research on traditional medicine.

Countries in the African Region are encountering problems in providing their people with equitable access to health care, and only about half of the population in the Region actually have access to conventional health care. Nonetheless, traditional medicine continues to be in popular use for historic and cultural reasons. Despite the use of traditional medicines for many centuries, challenges regarding the safety, efficacy and quality of traditional medicines exist, and the development of traditional medicine varies widely in different countries of the Region. That is why efforts must be redoubled to evaluate the safety, efficacy and quality of traditional medicines used in the treatment of the selected priority diseases as well as to regulate and streamline the activities of THPs in the Region.

In order to support Member States to meet some of these challenges, the WHO Regional Office for Africa has developed documents to be used as tools for institutionalizing traditional medicine in health systems. These documents are on policy development, implementation plan and registration of traditional medicines; regulatory and legal framework for the practice of traditional medicine; research methodologies; and protection of indigenous knowledge and traditional medicine. Some of these documents are being published separately to support countries to institutionalize traditional medicine in health systems. This document contains several tools.

Part I contains guidelines for formulating, implementing, monitoring and evaluating national traditional medicine policies. The purpose is to assist Member States to formulate and implement their national traditional medicine strategies and plans and to monitor key components of such policy implementation within the context of an overall national health policy. Part II contains a model legal framework for the practice of traditional medicine. The Traditional Health Practitioners Bill provides for the establishment of a Traditional Health Practitioners Council, a body that will be responsible for regulating the practice of traditional medicine.

Part III contains a model code of ethics for traditional health practitioners, including a code of practice, disciplinary procedures and minimum standards for the practice of traditional medicine in countries of the African Region. This is intended to assist countries wishing to fulfil their responsibility of ensuring effective utilization of traditional health practitioners for primary health care delivery and regulate their practice. Part IV provides guidelines for the formulation of a national master plan for the development of traditional medicine. This is a strategic plan which provides both a policy direction and a set of key priorities that has to be

implemented nationally in an integrated manner. The national master plan should be developed immediately after a national policy on traditional medicine has been formulated, as it should dovetail from the policy. The annex contains background, process and structural indicators for monitoring and evaluating utilization of traditional medicine.

I encourage countries to adapt the tools and guidelines in this volume for their specific situations because they include important suggestions that would lead to official formalization of traditional medicine. Understandably, considerable lessons will be learnt from implementation as time goes on. These will help to improve subsequent editions of the document. I therefore welcome your suggestions and encourage you to send them to the WHO Regional Office.

Dr Ebrahim Malick Samba  
Regional Director  
WHO Regional Office for Africa  
December 2003

## Preface

Following the recommendations of the forty-ninth session of the WHO Regional Committee for Africa held in Windhoek, Namibia in 1999, the WHO Regional Office for Africa developed a regional strategy document to contribute to the achievement of health for all through optimization of the use of traditional medicine. *Promoting the role of traditional medicine in health systems: A strategy for the African Region* was adopted by the fiftieth session of the Regional Committee held in Ouagadougou, Burkina Faso in 2000. One of the principles of the Regional Strategy is the institutionalization of traditional medicine (TM). The term *institutionalization* is used here to express the formalization and official incorporation of TM into national health systems and services. Institutionalization of traditional medicine in the countries of the WHO African Region would go a long way to enable traditional medicine to play the important role expected of it, as a viable supplement to conventional medicine, in health care systems, and thereby accelerate the progress towards achieving health for all in the Region.

The strategy urges Member States to actively promote, in collaboration with all other partners, the protection of intellectual property rights and indigenous knowledge in the field of traditional medicine. The traditional medicine resolution (AFR/RC50/R3) requested the WHO Regional Director to support Member States to:

- (a) Develop guidelines for the formulation and evaluation of national policies on traditional medicine;
- (b) Advise countries regarding the relevant legislation for the practice of traditional medicine; the documentation of practices and medicines of proven safety, efficacy and quality;
- (c) Strengthen WHO collaborating centres and other research institutions to conduct research;
- (d) Establish mechanisms for the protection of cultural and intellectual property rights.

These orientations can be achieved through institutionalization of traditional medicine, which calls for a number of actions to be undertaken by Member States. These include the setting up of professional traditional medicine bodies; the formulation of a code of ethics; the development of norms and standards; the establishment of mechanisms for the official recognition and support of traditional medicine, including the identification, registration and accreditation of qualified practitioners; and development of mechanisms of collaboration between conventional and traditional health practitioners. Therefore, the Regional Office has developed a number of documents to be used by countries for institutionalizing traditional medicine in their health systems. The Regional Office also prepared a number of guidelines and research protocols to be used by countries for institutionalizing traditional medicine in health systems based on country experiences and current trends (see references).

The First Meeting of the WHO Regional Expert Committee on Traditional Medicine held in Harare, 19-23 November 2001 reviewed the draft documents mentioned above. After their review by the WHO Regional Expert Committee, these draft documents were submitted to the regional meeting on Integration of Traditional Medicine in National Health Systems: Strengthening Collaboration between Traditional and Conventional Health Practitioners held in Harare, Zimbabwe, 26-29 September 2001. This meeting brought together national health authorities responsible for traditional medicine, directors of health services, drug regulatory authorities, biomedical researchers, academics and professional health associations, including traditional health practitioners, NGOs and partners from countries of the WHO African Region. This meeting was of the view that additional research protocols should be developed as well as a national implementation (strategic) plan for the development of traditional medicine.

Guidelines for the Formulation of a National Master Plan for the Development of Traditional Medicine and other documents were submitted to the Second Meeting of the WHO Regional Expert Committee on Traditional Medicine held in Libreville, Gabon in November 2002. The preparation of these guidelines forms part of the numerous efforts that the WHO Regional Office is making to promote the regulation of the practice of traditional medicine. They supplement other guidelines regarding intellectual property on indigenous knowledge and traditional medicine; registration of traditional medicines; documenting African traditional medicine and ethno-medical evidence; and evaluating traditional medicines used for the treatment of priority diseases such as malaria, HIV/AIDS, diabetes, hypertension and sickle-cell anaemia. Some of these guidelines are being published separately.

The draft guidelines on policy and regulatory framework, model code of ethics and master plan were adapted in some Member States (e.g. Madagascar, Mozambique, Nigeria, Sierra Leone and Tanzania) who participated in the above-mentioned meetings in the formulation of their national documents. Therefore, the guidelines were updated taking into account current trends and country experience. Subsequently, the four guidelines on policy formulation and implementation plan as well as on regulatory framework for the practice of traditional medicine and traditional health practitioners were combined into one document for easy reference by countries as tools for institutionalizing traditional medicine in their health systems.

## Purpose

The purpose of this document is to support Member States wishing to institutionalize traditional medicine in their national health systems. Specifically, the guidelines for a national policy on traditional medicine will assist Member States to formulate and implement their national traditional medicine strategies and plans and to monitor key components of such policy within the context of an overall national health policy. Its goals should therefore be consistent with broader health system objectives, and its implementation should support those objectives. The model legal framework is to assist Member States to enact laws to govern the practice of traditional medicine. It provides for the establishment of Traditional Health Practitioners Councils; regulatory frameworks to ensure the efficacy, safety and quality of traditional health care services provided by traditional health practitioners (THPs); and control over the registration, training and practice of THPs. Its goals should be consistent with broader national health legislation objectives, and its implementation should support those objectives.

The code of ethics for traditional health practitioners aims to assist Member States wishing to fulfil their responsibility of ensuring effective utilization of THPs for primary health care delivery and regulate their practice. It is meant to be used by governments to develop their own code of ethics in the context of their national health legislation. The guidelines for a national master plan is to assist Member States to formulate their national strategic plans from national policies and programmes that have to be implemented in an integrated manner.

### Target audience

The document is intended for use by competent national authorities responsible for the development and regulation of the practice of traditional medicine, experts in traditional medicine, professional health associations including traditional health practitioners and traditional birth attendants as well as other organizations involved in traditional medicine.

### Structure

This document contains four parts:

- Part I: Guidelines for national policies on traditional medicine
- Part II: Model legal framework for the practice of traditional medicine: A traditional health practitioners bill
- Part III: Model codes of ethics and practice for traditional health practitioners
- Part IV: Guidelines for the formulation of a national master plan for the development of traditional medicine

Bibliographic references that were used to support the preparation of the guidelines are provided at the end. An annex contains background, structural and process indicators to be used by countries to collect data on traditional medicine practices and utilization. Tools for institutionalizing traditional medicine in countries of the WHO African Region need to be adapted for specific situations. Understandably, considerable lessons will be learnt from the implementation of this document by Member States. The lessons will serve as input for improving subsequent editions.

## Abbreviations

ADB	African Development Bank
AU	African Union
CAM	Complementary and alternative medicine
CIDA	Canadian International Development Agency
FAO	Food and Agriculture Organization
GCP	Good clinical practice
GDP	Good distribution practice
GDP	Gross domestic product
GMP	Good manufacturing practice
HIV/AIDS	Human immunodeficiency virus/Acquired immunodeficiency syndrome
IUCN	The World Conservation Union
IPRs	Intellectual property rights
MOH	Ministry of Health
NAC	National Advisory Committee
NGO	Nongovernmental Organization
NMB	National management body
NTF	National Taskforce
PEC	Professional Ethics Committee
PHC	Primary health care
SMART	Specific, measurable, achievable, realistic and time bound
SWOT	Strengths, weaknesses, opportunities and threats
TBA	Traditional birth attendant
THP	Traditional health practitioner
THPAZ	Traditional Health Practitioners Association of Zambia
TM	Traditional medicine
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TRM	Traditional Medicine Programme
UNIDO	United Nations Industrial Development Organization
WHA	World Health Assembly
WHO	World Health Organization
WIPO	World Intellectual Property Organization



# Part I : Guidelines for National Policies on Traditional Medicine

## 1.1 FORMULATION AND IMPLEMENTATION OF A NATIONAL TRADITIONAL MEDICINE POLICY

As a follow-up to the policy orientations of *Promoting the role of traditional medicine in health systems: A strategy for the African Region* [1] adopted at the fiftieth session of the WHO Regional Committee for Africa in Ouagadougou in 2000, the Regional Office has developed this guide for national traditional medicine policies. It is based on the experiences of Member States in the development of national drug and traditional medicine policies and plans [2-4]. A national policy on traditional medicine should derive from and support a national health policy.

Since traditional medicine is used by the majority of the population in the African Region, governments should re-position traditional medicine and give appropriate recognition and support to improve the image and standard of traditional health practitioners. This can be done through policy changes, regulations and registration of traditional health practitioners, as well as fostering collaboration between conventional and traditional health practitioners.

A national policy on traditional medicine will define the role of traditional medicine in health care delivery system, and commit the direction and action of government's involvement in traditional medicine. Development of a national policy on traditional medicine and programmes should be considered as an integral part of the efforts for health system development.

Member States should take advantage of WHO commitment and African Union resolutions and declarations to develop African traditional medicine in countries of the Region.

## 1.2 THE FORMULATION OF A NATIONAL POLICY ON TRADITIONAL MEDICINE

### Definition

A national policy on traditional medicine is a guide for action-containing goals set by the government and the main strategies and approaches for attaining them. The goals will indicate the government's view on the role of traditional medicine (TM) in promoting and maintaining health and its position on its development and utilization in the general health service system. Safety, efficacy and quality of TM should be stated as the guiding principle. The policy should be part of the national health policy and its strategies should be based on the major priority problems identified during the situation analysis on TM. The national TM policy provides a framework to coordinate activities related to the development of TM in the public sector as well as the private sector as practised by traditional health practitioners (THPs), donors, nongovernmental organizations (NGOs) and other interested parties.

Regardless of the country's circumstances, a comprehensive national policy on TM should be concerned with the delivery of the maximum level of efficient services, given a certain level of resources, fairness in access to TM or equity, and the ability to continue to provide its benefits in the future without external support.

## Objectives

The objectives and strategies may differ from country to country due to differences in the structure of the health care system, the current development of the traditional medicine sector, the number of trained conventional health workers, the availability of financial resources, training infrastructure, level of collaboration between modern and THPs, the ratios of traditional health workers and conventional health workers to the population, and the health priorities set by the government.

Countries may wish to consider some of the following specific objectives:

- (a) To regulate the practice of traditional health practitioner's as well as traditional medicines with a view to protecting the population from quackery, fraud, and incompetence;
- (b) To provide a framework on proper actions for bringing traditional medicine and its practice into health sector development;
- (c) To establish a country-specific institutional framework for the practice of traditional medicine;
- (d) To develop and facilitate the use of traditional medicine in the country;
- (e) To underscore the contribution of traditional medicine to health care delivery.

## Purpose

There are many reasons why a country should formulate a national policy on TM. These include the following:

- (a) To define national objectives this must be met in order to improve health, economic, and the development and the impact of TM on the health system.
- (b) To determine standards and values on which all actions in the health technology area will be based.
- (c) To ensure government's commitment in the direction and provision of financial and other resources.
- (d) To commit the direction and global orientation towards which all actions of TM will be oriented.
- (e) To regulate the practice of traditional health practitioners and to ensure the safety and quality of TM.
- (f) To identify strategies to be implemented to achieve the goal of improving health outcomes through a more rational use of TM.
- (g) To safeguard TM as a national heritage with widespread use in some areas and as the only form of health care available.
- (h) To identify strategies that shall be implemented to achieve the goals and objectives for improving the national situation of traditional medicine.

- (i) To protect the patient from standard care and to protect traditional health practitioners.
- (j) To recognize the role of THPs and define their rights, privileges and responsibilities as health care providers
- (k) To educate and guide the THPs and the community
- (l) To correct the serious neglect in the education and training (including continuing education) of THPs and in research on the effectiveness of their practices)
- (m) To protect THPs from malpractice suits and prosecution under existing and proposed penal laws in some countries.
- (n) To protect individuals and the community from charlatans.

### 1.3 THE PROCESS OF FORMULATING A NATIONAL POLICY ON TRADITIONAL MEDICINE

The process for the formulation of a national policy on TM may vary from country to country. Experience from Member States within and outside the African Region indicates that the formulation of a national policy on TM has a number of interconnected phases and steps (Figure 1). Table 1 summarizes the process for the formulation of a national policy on traditional medicine discussed in different phases and steps. Each Council, Board or Committee shall consider specific indicators for monitoring and evaluation of the instruments for institutionalizing traditional medicine in health systems.

#### PHASE 1: SETTING AN AGENDA

##### Step 1 : Political commitment

The government's political commitment is the starting point before formulating a national policy on TM, which should be a part of the country's national health policy. Heads of State of Member countries are expected to make definitive statements regarding recognition, sociocultural importance, development and support for traditional medicine and the rich African biodiversity. Political commitment is expressed through the national health authority or another competent authority for TM which launches the formulation process by establishing a national taskforce (NTF), advisory committee (NAC), management body (NMB) or similar body to coordinate traditional medicine activities.

##### Step 2 : Establishment of a national taskforce, advisory committee or management body

The national health authority may establish an advisory committee to assist in the formulation of a national policy on TM. If required, subcommittees to advise on specific aspects of the proposed policy could support the advisory committee. The committee should be composed of an interdisciplinary group such as academics, botanists, conventional health practitioners, conservationists, cultivators, health economists, journalists nurses, lawyers, managers of TM units, professional associations, pharmacists, THPs, planners and where appropriate, directors of WHO collaborating centres for TM.

The responsible ministry should define the terms of reference for the committee in order to render it operational and provide the required resources for policy formulation. If the ministry does not have the required resources, financial support may be requested from bilateral and multilateral agencies.

### **Step 3 : Information campaign**

The results of the information campaign will enable the government to understand and appreciate the role of TM in the community and will increase awareness about policy. The NTF, NAC or NMB, in collaboration with appropriate government agencies such as associations of THPs and experts in traditional medicine, should undertake these activities related to information dissemination.

### **Step 4 : Social marketing**

An important function of the NTF/NAC/NMB involves informing the public on traditional medicine through social marketing activities. The government could undertake these activities with support from experts, health professional associations and THPs. Posters and other written materials could be prepared and distributed. Community-based educational activities could be organized and the media, such as newspapers, radio and television, could be used to support the efforts of social marketing. The assistance of newspaper editors or producers of radio and television programmes is invaluable in ensuring full coverage. Personal interviews or interactions with the media will be most productive.

### **Step 5 : Country situation analysis**

The NAC coordinating TM activities should undertake a systematic review of the situation of traditional medicine in the country. This analysis should cover all the components of a national health policy. The situation analysis will also provide information on the current political, socioeconomic, cultural and developmental status. The NAC will analyse data and identify the strengths, weaknesses, opportunities and threats (SWOT) related to the integration of TM in the country's health services, with specific emphasis on the major priority problems identified. The objectives of undertaking a country situation analysis of TM are to:

- (a) Describe the current situation of TM in the country.
- (b) Define the existing policy framework regulating THPs, and their practice of TM
- (c) Define the organizational aspects of traditional medicine such as existing associations of THPs, management bodies and TM units/departments in relevant ministries.
- (d) Identify constraints adversely affecting the institutionalization of TM.
- (e) Propose ways of improving the performance of the traditional health care delivery system.

The situation analysis can also make use of background, structural and process indicators for monitoring and evaluating the utilization of traditional medicine in the country (see Annex 1).

## PHASE 2: POLICY FORMULATION

### Step 1 : Preparation of a strategic plan

A strategic plan should be developed as part of overall planning. Following the identification of strengths, weaknesses, opportunities and threats (SWOT) from the situation analysis, priorities can be set and the objectives better defined. The adoption of a strategy is very important as it may involve a choice between several approaches.

### Step 2 : Preparation of a draft policy

The NAC, NTF or NMB should be given the responsibility to draft the policy document. The document should be based on the findings of the country's situation analysis. The content of a national policy medicine is described below.

### Step 3 : Consultation with experts

The NAC, NTF or NMB should use the services of relevant experts as a deliberate operational practice. Where necessary the NAC should seek expert opinion on the draft policy from within the country, regional sources, from WHO and other international bodies before holding a national consensus workshop.

### Step 4 : National consensus workshop

Consultation with the communities and interested parties is essential. The NAC should organize a 3–5-day national workshop and other consultation processes to discuss the draft policy and to collect comments and suggestions, under the auspices of a national health authority. Where necessary, expert opinion should be sought from WHO and other international or regional sources. All interested parties in both the private and public sectors should be involved and invited to the workshop. These may include professional groups, universities, research institutions, manufacturers of traditional medicines, conservationists of medicinal plants, traditional health and conventional practitioners, botanists, relevant non-governmental organizations and bilateral and multilateral agencies. The workshop should review the document and provide general orientations, including adoption of objectives and strategies for each component of the draft national policy.

### Step 5 : Finalization of the policy document

The NAC should revise the draft policy document in accordance with the recommendations of the national workshop, after which it should be finalized and submitted for formal government endorsement and adoption. Some participants should assist in the finalisation of the said document.

### Step 6 : Policy document approval, endorsement and adoption

The completed document should be transmitted to the national health authority, which will submit it to the competent body for approval, endorsement and adoption. Based on this document, a law to support and regulate the national policy should be enacted.

### Step 7 : Printing and dissemination of the official document

The official national policy should be printed in sufficient numbers for wide distribution to all stakeholders in both the public and private sectors.

### Step 8 : Launching and wide distribution

The national policy on traditional medicine should be officially launched for advocacy purposes. The document should then be widely distributed and promoted in various seminars for effective implementation. In view of the peculiarity of traditional medicine regarding the literacy status of traditional health practitioners, efforts should be made to translate the national policy into other local languages.

## PHASE 3 : POLICY IMPLEMENTATION

### Step 1 : Planning for the implementation of a national policy on traditional medicine

Planning should be carried out in terms of the necessary resources (human, financial and material), the institutional framework and a monitoring and evaluation system for the implementation of the policy on traditional medicine.

The following are the requirements (prerequisites) for facilitating the implementation of the national policy on traditional medicine:

Expected outcomes	Indicators
Policy document approved and endorsed	NAC, NTF or NMB established
Policy document launched and distributed	Situation analysis completed; strategic plan prepared and drafted; national consensus workshop held

A Traditional Medicine Unit or a similar structure should be established by an appropriate ministry to be responsible for the implementation of the national policy on traditional medicine. The national health authority should establish a multidisciplinary and multisectoral team to monitor and evaluate the implementation of the national policy and to advise on issues related to traditional medicine. The national policy should be widely distributed and promoted to all stakeholders such as relevant ministries, traditional health practitioners and their associations, manufacturers of traditional medicines and pharmaceuticals, members of parliament, NGOs, national and regional and international organizations involved in the development of traditional medicine. The national authority should provide adequate resources for the multidisciplinary and multisectoral team to carry out an effective mission. If necessary, extrabudgetary funding can also be mobilized to ensure that resources are made available that are required to support the work of the above-mentioned team. The NAC should prepare a five-year plan of action which should be monitored every year.

## Step 2 : Development of a strategic plan for implementation

A strategic plan for the implementation of the national policy should be developed. The specific strategies to be adopted will depend on the national and local situations, including the accessibility of the existing health care system; the acceptance levels for traditional medicine by the dominant health care providers; the type and formal organization of the traditional medicine modalities and practitioners; social views on and acceptance of traditional medicine; and economic factors. Since each country has unique characteristics, the strategies to be developed must be specific for that country.

**Figure 1: Phases and steps in the formulation, implementation, evaluation and monitoring of a national policy on traditional medicine**

<b>POLITICAL COMMITMENT</b>	
<b>PHASE 1: SETTING AN AGENDA</b>	
<b>Steps</b>	
1.	Political statement by Head of State
2.	Establishment of a National Advisory Committee
3.	Information campaigns
4.	Social marketing
5.	Situation analysis
<b>PHASE 2: POLICY FORMULATION</b>	
<b>Steps</b>	
1.	Preparation of a strategic plan
2.	Preparation of draft policy
3.	Consultation with experts
4.	National consensus workshop
5.	Finalization of policy document
6.	Approval and endorsement of the document
7.	Printing and dissemination of the official document
8.	Launching and wide distribution
<b>PHASE 3: POLICY IMPLEMENTATION</b>	
<b>Steps</b>	
1.	Planning for implementation
2.	Establishment of an operational administrative structure
3.	Formation of a multidisciplinary and multisectoral team
4.	Distribution and promotion of national policy
5.	Allocation of resources for implementation
6.	Preparation of a 5-year action plan
7.	Development of a strategic plan
8.	Allocation of financial resources
9.	Implementation of the national policy
<b>PHASE 4: POLICY EVALUATION AND MONITORING</b>	
<b>Steps</b>	
1.	Monitoring and evaluation
2.	Periodic review of policy taking into account TRIPS and other new developments

### Step 3 : Allocation of financial resources for implementation

Financial resources from local, regional and national authorities should be allocated to support the implementation of the policy. If necessary, additional resources may be requested from WHO and other international organizations.

### Step 4 : Implementation of the policy

Once the NAC has been established, an appropriate strategic plan adopted, and funding secured, actions must be taken to implement the national policy on traditional medicine. The governmental agency will undertake the initial actions, followed by THPs and other health care provider organizations, community NGOs, universities and other academic institutions and researchers.

Expected outcomes	Indicators
Traditional medicine used properly and contributing to national health goals	Strategic plan for implementation of TM policy prepared; framework for policy implementation developed; necessary resources allocated

## PHASE 4: POLICY MONITORING AND EVALUATION

### Step 1 : Monitoring and evaluation

As in the case of any policy, the national policy on traditional medicine must be monitored and evaluated periodically. The national council or advisory committee should consider specific indicators for monitoring and evaluation of the tools for institutionalizing traditional medicine in health systems. External expertise may be sought from WHO, partners (e.g. UNIDO, GEF, FAO) and through bilateral collaboration.

### Step 2 : Periodic review of the national policy taking into account TRIPS

Depending on the evaluation results, periodic reviews of the national policy may be necessary to achieve its stated goals and objectives, taking into account the trade-related aspects of intellectual property rights (TRIPS) elements particularly those laid down in Article 27.3(b) vital for legal recognition of indigenous knowledge and traditional medicine [5-6].

Expected outcomes	Indicators
Legislation and regulations on TM practice established	National TM policy implemented

**Table 1: Process for formulating a national policy on traditional medicine**

Step	Responsible body	Actions	Expected outcomes
<b>PHASE 1: SETTING AN AGENDA</b>			
1. Government political commitment	Government, MOH or other appropriate authority	Recognize the role of TM in health systems	Decision to formulate a national policy
2. Establish NTF, NAC or NMB	MOH or other national authority	Allocate resources	NTF, NAC or NMB created
3. Country TMsituation analysis	MOH or other national authority	Data collection and analysis	Storage of country situation analysis data
4. Information campaigns	THPs, experts, professional organizations, appropriate government agencies	Information campaigns	Policy-makers aware of role of TM in health systems
5. Social marketing	Government, experts, THPs, professional associations	Preparation, distribution of posters and other visual materials; educational activities; public media: newspapers, radio, TV	An informed public
<b>PHASE 2: POLICY FORMULATION</b>			
6. Preparation of a strategic plan	MOH, Taskforce, other experts	Prepare and review strategic plan	TM strategic plan developed
7. Preparation of the draft policy	Taskforce, other experts	Prepare draft policy	Draft national policy developed
8. National consensus workshop	MOH, other appropriate authority, Taskforce, parties concerned	Review and adopt the draft national policy	Draft national TM policy adopted; ideas exchanged between experts and partners
9. Finalization of draft policy document	Taskforce, workshop participants	Amend draft national policy	Final national policy document
10. Approval and endorsement of a national policy	Government workshop participants	Review of final national policy	National TM policy document officially approved
11. Printing	Taskforce, MOH	Print the national policy document	National policy document printed
12. Launching, distribution and promotion	Taskforce, MOH	Distribute policy; hold policy promotion seminars; disseminate information on policy via media	Interested parties informed; general public sensitized

<b>PHASE 3: POLICY IMPLEMENTATION</b>			
13. Planning policy implementation	Taskforce, MOH	Plan national TM programme; strengthen the TM Unit; mobilize resources	Taskforce ready to implement national TM policy
14. Developing a strategic plan for policy implementation	Taskforce, MOH	Develop a country-specific strategic plan for implementation of the national TM policy	Strategic plan for implementation developed
15. Allocation of financial resources	Local, regional, and national authorities	Allocate financial resources; mobilize additional resources	Financial and other resources allocated and mobilized
16. Implementation action	Government agency, THPs, other health care providers, organizations, communities, NGOs, universities, researchers	Implement the national TM policy	National TM policy implemented
<b>PHASE 4: POLICY MONITORING</b>			
17. Monitoring and evaluation	Taskforce, MOH	Monitor and evaluate implementation; mobilize resources	National TM policy monitored and evaluated
18. Periodic review of policy, taking into account TRIPS	Taskforce, MOH	Review TM policy; mobilize resources for policy review	National TM policy reviewed; resources for review mobilized

## 1.4 STRUCTURE OF A NATIONAL POLICY ON TRADITIONAL MEDICINE

The content of a national policy on traditional medicine will vary from country to country due to differences in the level of development of traditional medicine, availability of resources and political commitment. However, the policy should address problems identified during the situation analysis. The role of the government includes identification of the need for a national policy, development of a policy statement, development of a strategic plan, implementation of the national policy, and evaluation and monitoring.

In general, a national policy on traditional medicine should include a statement of the government's role in the development of traditional medicine in the health care delivery system. The policy should include the vision and mission as well as goals and objectives for traditional medicine policy. A national policy on traditional medicine may contain the following sections:

### Introduction

The introduction should consist of a short description of the geographical, economic, epidemiological, social and demographic characteristics of the country. It should also contain a summary of the contents of the national policy on traditional medicine.

### ***History and situation of traditional medicine in the country***

This section should briefly describe the current situation of traditional medicine in the country as well as policies earlier adopted and institutional and operational strategies, if any, related to traditional medicine. This section should also describe the priority health problems identified in the situation analysis which will be tackled by the national policy on traditional medicine.

### Preamble

The foundations and principles of a national policy on traditional medicine should be described. In particular, the organizational and political provisions already adopted to implement the principles in the health system in general and traditional medicine field, such as:

- (a) The country's adherence to the 1978 Alma-Ata Declaration on primary health care strategy which recognized the use of traditional medicine and its practitioners as important actors for achieving health for all [7].
- (b) The country's adherence to *Health-for-All policy for the 21st century in the African Region: Agenda 2020* [8].
- (c) The country's adherence to the implementation of the regional strategy, *Promoting the role of traditional medicine in national health systems (AFR/RC50/9)* [1].
- (d) The country's adherence to the implementation of the plan of action of the African Union for the decade of African traditional medicine [9].

The preamble should also indicate the place of traditional medicine within the context of the national health policy and relevant reforms undertaken under structural adjustment

programmes affecting the social and economic aspects of the country and how traditional medicine has been instrumental in them. The national policy on traditional medicine should spell out the vision and mission or intent and objectives of the government. The vision of the government on traditional medicine may include the following points:

- (a) Definition of traditional medicine (to emphasize its cultural heritage and social and economic values);
- (b) The place and role that traditional medicine could play in the health system, in particular its role in improving the quality of the country's health care system;
- (c) The role of traditional medicine in the country's economic and social development;
- (d) The principle of equity and equal access by all citizens to health care in general and the percentage of the population which have access to conventional health care and traditional medicine services;
- (e) The position and interface between traditional medicine and allopathic medicine in the country's health care system.

The government's mission statement may include the following points:

- (a) Regulation of the practice of traditional health practitioners, provision of infrastructure, development of a code of ethics for traditional health practitioners;
- (b) Education and training of traditional and conventional health practitioners;
- (c) Regulation of raw materials processed and finished products;
- (d) Acceptable standards of safety and quality of traditional medicine practices and medicines;
- (e) Promotion of the proper use of traditional medicine, particularly in primary health care delivery systems;
- (f) Need for new legislation or expansion of existing laws in the country;
- (g) Capacity building to strengthen government expertise in traditional medicine;
- (h) Conservation of medicinal plants, animals as well as application of national or international conventions on biodiversity and endangered species);
- (i) Promotion and advocacy of the role of traditional medicine in health care systems (including dissemination of information inside and outside governments);
- (j) Research and development;
- (k) International technical cooperation and exchange;
- (l) Monitoring and evaluation of the implementation of the national policy on traditional medicine.

## General orientation

This section should contain general guidelines concerning the development of the national policy, the objectives and strategies to be used for achieving the objectives as well as the country's plans for the development of traditional medicine.

## Goals

The overall health-related goals of the national policy on traditional medicine in most cases should be very general. In one African country, for example, the goal of the policy states that "In pursuance of the goal of the National Health Policy, which is to harness all available resources for health care delivery, it is envisaged that traditional medicine would constitute one of the veritable means of promoting Health for All by the year 2010 as enunciated in the National Health Policy and the National Health Plan". In another African country, the goals are "to promote the appropriate use of traditional medicine and to encourage the integration of traditional medicine into the mainstream health service system".

Economic-related goals may be to reduce the use of foreign currency for the importation of conventional medicines or to provide jobs in areas such as conservation and harvesting of medicinal plants; pre-packaging; and local production of traditional medicines. Other economic-related goals may be to build capacity in areas such as the utilization of medicinal (and aromatic) plants in accordance with good agricultural and collection practices [10]; formulation, production, distribution and use of traditional medicines following good manufacturing practice (GMP), good clinical practice (GCP) and good distribution practice (GDP).

National development goals could be the improvement of the health and welfare of the population or elaboration of a framework to enable the formulation of appropriate legislation and regulations for the operation of traditional medicine programmes.

At the same time, there should be consideration of the following key ethical issues:

- (a) Respect for the person as an individual and for the community as a whole;
- (b) Promotion of the beneficial effects of traditional health care and elimination of the harmful ones;
- (c) Promotion of social justice through ensuring safe, culturally acceptable and cost-effective traditional health care;
- (d) Protection of intellectual property rights and indigenous knowledge as well as equitable benefits for individuals and communities;
- (e) Education and training of both conventional and traditional health practitioners in traditional medicine;
- (f) Research and development.

## Objectives

The objectives of different components of traditional medicine should be defined. These objectives should derive from priority problems related to traditional medicine identified during the situation analysis as well as policy options which the government wants to address. The targets for a determined period can also be defined in this section.

## Strategies

A good national policy on traditional medicine should present approaches or strategies for achieving the goals of the policy. The strategies required to achieve the objectives of the policy should be developed. For each objective, external and internal constraints should be identified and appropriate strategies defined. The activities to be performed to implement country strategy should be outlined, and expected outcomes should be stated. For instance, if the government objective is to explore the potential contribution of scientifically-proven traditional medicines in the national health care system, the strategies, activities and expected outcomes for attaining this objective should be clear (Box 1).

### Box 1: A sample objective

**Objective: To explore the contribution of scientifically proven traditional medicines in the national health care system**

**Strategy A: Using existing research outcomes**

**Strategy B: Conducting research on traditional medicine**

In the case of evaluation of traditional medicines, WHO agreed research protocols should be used [14-15]. Harmonizing traditional and modern medicine will ensure their proper and effective employment as companion treatment modalities.

#### **Activities**

##### **1. Information exchange**

Develop systems of information exchange between Member States of the African Region. All scientific information on medicinal plants and traditional medicine practices should be assembled and computerized in a database. Videos, recorded tapes, books, brochures and other print materials should be provided by governments and organizations on a regular basis. Information dissemination by stakeholders can be effected through newsletters, videos, tape recordings, websites and publication of scientific findings. Regional or national seminars, meetings and workshops sponsored by professional organizations, NGOs, government or international organizations also provide effective means and forums for information exchange.

##### **2. Sound, methodical research**

Development and adoption of an evidence-based approach should clarify the extent and limitations of the practice of traditional medicine.

**3. Social marketing and advocacy**

Ministries or departments of health, NGOs, professional organizations and others can undertake these activities through electronic and/or print or broadcast media.

**4. Annual exhibitions or conferences in traditional medicine**

Behavioural and lifestyle changes of the service providers and recipients are likely outcomes of social marketing and advocacy.

Strategies for improving the national policy on traditional medicine should include development of communication and information networks. These should provide a computer network and website facilities at country level. This network will then be linked to the WHO Regional Office for Africa website and other databases in the African region. Ethnobotanical and pharmaco-epidemiological studies should be carried out in specific geographical areas to provide data on the disease patterns. Pilot clinical studies should be conducted on the most promising plants and medicines, followed by full clinical trials. Then, medicines with acceptable safety and efficacy indices should be developed for gradual application.

**1.5 CONTENT OF THE POLICY**

Depending on the stage of development of traditional medicine in a country, it may wish to provide information in the policy identified in the situation analysis. This may include legislation and regulations; education and training; research and development; local production of traditional medicines; ethical issues; allocation of resources; health information system, intellectual property rights for protection of indigenous knowledge, regulation on access to and utilization of medicinal plants; incorporation of national laws on the Convention on Biodiversity and conservation of medicinal plants; cooperation among traditional health practitioners; technical cooperation among countries; monitoring and evaluation.

**Government roles**

The Ministry of Health and other relevant government agencies have major roles to play in most matters of health, including traditional medicine. The MOH also has the responsibility of providing appropriate resources for the implementation of policy. Government roles include the establishment of safety and educational standards, funding for research and training (both primary, secondary, tertiary and continuing education), registration and regulatory rules and agencies, quality assurance and quality measures, intellectual property rights protection and promotion.

Expected outcomes	Indicators
Safer and more effective medical treatment for people	Public announcements
Laws and regulations to empower and protect traditional health practitioners enacted	Availability of legal framework and regulations for the practice of traditional medicine in countries functional; Availability of Traditional Health Practitioners Council

## Legislation and regulations

Legislation on traditional medicine should enable the recognition of THPs through support activities on traditional medicine and creation of an enabling environment for their practice. It should also provide THPs' recruitment, registration, rights, privileges and responsibilities as well as modalities for their effective utilization in health systems, particularly in primary health care. Laws should define and standardize basic concepts of traditional medicine and define areas of practice. Provision should be made for enactment of laws to protect the practice of the profession, as well as to stipulate the appropriate *materia medica* upon which traditional medicine should depend for its growth and survival.

The registration of THPs and the promulgation of regulations for their practices are legal issues to be addressed by an appropriate authority such as governments at local and national levels. These measures are designed for the protection of the patient and consumer to ensure that the practitioner is fully qualified. Laws and regulations to empower and protect THPs have to be enacted. These legal rights allow THPs to benefit from adequate compensation for their knowledge. There are many options for regulation of THPs. These range from professional organizations imposing standards on their own members to recognition of these standards, either directly or indirectly, by the government, including statutory support for bodies which impose these standards or formal government registration of practitioners by law. As an initial step towards establishment of a legal framework, an association of THPs should be created and this body or an appropriate authority may register THPs.

Regulation of traditional medicines should be provided for in the legislation which should recognize specific issues such as traditional history of use or current (unregulated) usage in the community. In principle, the long history of use of a traditional medicine should in most cases be adequate evidence of its safety provided that its proposed application reflects its historical use. Detailed information on the regulation of traditional medicines has been published by WHO [11].

Expected outcomes	Indicators
Government registration system established	Establishment of government registration system
Management or regulatory bodies that exclusively handle traditional health practitioners created	Creation of management or regulatory bodies that exclusively handle traditional health practitioners
THPs included in conventional-oriented health professional regulatory commissions or equivalents	Inclusion of traditional health practitioners in conventional-oriented health professional regulatory commissions or equivalents
Self-imposed initial process of registration by organization of THPs or self-funded and monitored	Laws enacted to regulate access to medicinal plants

## Code of Ethics

Establishment of the code of ethics for the practice of traditional medicine, whether at district, village, community, regional or national level, should take into account traditional, customary beliefs, norms, taboos, rules and attitudes. Codes of ethics and practices are fundamental requirements to protect the rights of the patient and to ensure that the patient receives optimal care. To ensure that the practice of traditional medicine is respectable, fundamental human rights must be codified and adhered to. These should include the protection of the individual; confidentiality in practice; informed consent in studies and clinical trials; respect for the dead; respect for proprietary rights and intellectual property; adequate compensation (for practitioners' services, malpractice suits); promotion of national resource regeneration and conservation; and avoidance of prejudice against patients. Since codes are not legal instruments, they must be established and publicized by traditional health practitioners and their organizations.

The national body responsible for the regulation of traditional medicine, various associations of THPs and the national body responsible for the protection of human subjects in research should be in charge of ensuring ethical conduct in the practice and research in traditional medicine.

Expected outcome	Indicators
Adherence to codes of ethics by THPs resulting in safe and effective medical treatment of the patient	Development of codes of ethics and of practice by the government body responsible for traditional medicine
	Publications of codes of ethics (including code of practice)

## Education and training

Continuing education and training in traditional medicine should promote acceptance and recognition as an integral part of the cultural heritage of the people, and it should facilitate collaboration between the modern and traditional systems. Countries are encouraged to adapt various documents to their own situation [12-13]. Education and information about traditional health care and its practitioners should be introduced into medical, nursing and other health science curricula, as well as in social and behavioural sciences. Students of both systems should be involved in multidisciplinary action research in traditional and modern medicine. Appropriate information about the philosophy, principles, history and cultural value of traditional medicine (merit and limitations) and the role of its practitioners in national health care should be included in secondary school curricula and introduced in the training courses for teachers.

Selected THPs should be invited to explain and discuss their work with students and teachers. The complementary aspects of the modern and traditional health systems within a community must be emphasized to the practitioners of both systems in order to promote mutual professional respect. Special training of traditional health practitioners for their participation in certain primary health care programmes must be emphasized.

Expected outcomes	Indicators
Development of training programmes	Aspects of traditional medicine included in all curricula
Development of training materials for health science institutions, school children and teachers, THPs and community	Continuing education for practising conventional and traditional health professionals through workshops, seminars, formal courses and consultations with funding from NGOs; public, private, WHO and other partner organizations
Certification of training courses; improved standards of practice	Number of training institutions that have adapted the WHO tools for CHPS and health science students
Development of continuing education programmes	Number of countries that have developed training programmes WHO based on tools for continuing education of THPS in PHC

## Financial resources

A policy should be formulated to provide adequate funding from national budgets to ensure the active involvement of traditional health practitioners in national health care delivery. External sources of funding should only be considered as secondary or supplemental resources to the normal government expenditure. Financial resources should also be made available for public education and information and for the training of THPs through both the formal health system and associations of THPs. Budgetary allocation should be provided for traditional medicine in national health budgets, as well as in the Traditional Medicine Unit, where appropriate. Adequate financial support is a key factor in the effective implementation of policies, programmes and projects aimed at promoting the utilization of THPs in primary health care.

Expected outcomes	Indicators
Financial resources for public education and information allocated	Allocation of financial resources for public education and information
Financial resources for training of THPs allocated	Allocation of financial resources for training of traditional health practitioners
Financial resources for implementation of policies, programmes and projects allocated	Budgetary allocation of resources for traditional medicine activities
Financial resources for Traditional Medicine Unit allocated	Allocation of financial resources to the Traditional Medicine Unit by the government/MOH

## Research and development

The importance of research as the source of new information for establishing community diagnosis, determining needs and resolving community health problems must be emphasized in the development of a policy for the promotion of traditional medicine. Therefore, a national research policy should be formulated and implemented by a multidisciplinary traditional medicine research council that includes among its members, from the planning and implementation of research to the discussion and evaluation of results. Feedback of research results to all personnel and institutions involved in the project should be ensured. THPs should be treated with respect, adequately compensated for their participation and duly acknowledged. National authorities should support multidisciplinary clinical studies on the safety and efficacy of traditional remedies in the treatment or management regimens of priority conditions. All research must respect ethical principles. Academic and research institutions should be encouraged and funded to take an initiative in these efforts. Various kinds of research are necessary for full and balanced development of traditional medicine.

Various WHO documents contain research protocol to produce evidence on quality, safety and efficacy of traditional medicines [14, 15]. These documents combine safety protocol with treatment of uncomplicated malaria, HIV/AIDS, hypertension, diabetes and sickle-cell anaemia. WHO will continue to develop and update research protocols and guidelines on research methodologies for evaluation of traditional medicine for adaptation by different countries, to facilitate evaluation, comparison and follow-up of results.

Expected outcomes	Indicators
Representation of THPs in national health research bodies and councils	Formulation of a national health policy which includes a national health research policy and traditional medicine research policy by countries
Development of compensation mechanisms such as agreements for benefit sharing, Memoranda of Understanding for participation of THPs in research projects	Multidisciplinary action research on evaluation of safety, efficacy and quality of traditional medicines and operation research undertaken by countries
Implementation of a national health research policy by a multidisciplinary team which includes traditional medicine research policy	Formulation of a national traditional medicine research policy by countries

## Integration of traditional medicine into primary health care

Ministries of health, traditional health practitioners, NGOs and patients can carry out the promotion of the use of traditional medicine in primary health care. The integration of traditional medical practices into national health care systems requires not only the acceptance and support of governmental and non-governmental agencies and advocacy groups, but, also of the practitioners of conventional and traditional medicine.

Expected outcome	Indicator
Recognition, acceptance and support of TM as a component of a nation's health care system; establishment of institutions or offices to oversee development of TM	Regular public dialogues, seminars and workshops

## Intellectual property rights

The preservation of traditional medical knowledge and the biodiversity of natural resources such as medicinal plants, which affect all stakeholders, requires legal action. Countries need to establish policies that guarantee the intellectual property and patent rights of individuals and institutions involved in research and development of new drugs from traditional remedies. Such a policy should indicate how income potentially arising from these discoveries should be distributed. The appropriate government authorities must enact proper laws if they are not already in place. Bilateral and multilateral agreements between and among traditional health practitioners, researchers, NGOs, government agencies, companies and countries for the sharing of knowledge and royalty returns are required. Legislation on intellectual property rights (IPRs) should be based on the Convention on Biological Diversity and Trade-Related Aspects of Intellectual Property Rights (TRIPs), the OAU model law and WHO guidelines on IPR [5-6].

Expected outcomes	Indicator
Creation of patent and trademark systems for traditional medicines and practices	Bilateral or multilateral agreements between and among THPs, researchers, NGOs, government agencies, companies and countries for the sharing of knowledge and royalties
International agreements regulating access to medicinal plant resources for pharmaceutical research	Number of countries that have developed or reviewed legislation for protection of IPRs and TMK using WHO guidelines

## Conservation

There are currently neither national policies nor legislation on conservation of medicinal plants. There is therefore an urgent need for clear and well-focused policies backed by appropriate legislation on conservation of medicinal plants. Such legislation should be directed towards the conservation and rational utilization of traditional medical resources, including vegetable, animal and mineral products, upon which many traditional health practitioners depend. The conservation of the environment, biodiversity, knowledge, skill and culture affects all stakeholders, from the individual to the world at large. The responsibility for conservation also rests on the individual as well as on the global community. Resources for such effort

may be derived from the local community, traditional medicine associations, private sector donors, NGOs and government organizations.

Expected outcome	Indicators
Biodiversity and knowledge, skill preserved	Botanical, herbal and home gardens established; medicinal plants conserved; scientific publications on conservation published and available

### Ownership of African medicinal plants

Medicinal plants are owned by the state, community or individual persons. It is necessary to recognize state, community and individual rights of ownership, taking into account state sovereignty. Countries should enact laws to regulate access to medicinal plants and make sure that these are enforced by institutions, including the judiciary. Countries must establish central clearinghouse mechanisms for access and for both internal and external transfer of medicinal plants.

Expected outcomes	Indicators
Laws and regulations to empower and protect THPs enacted	Development of laws and regulations to empower and protect THPs
Laws to regulate access to medicinal plants enacted	Development of laws to regulate access to medicinal plants
Establishment of central clearinghouse mechanisms for access purpose	Central clearinghouse mechanisms for access purpose, established or strengthened
Establishment of mechanisms for addressing internal and external transfer of medicinal plants	Mechanisms for addressing internal and external transfer of medicinal plants, established or strengthened

### Establishment of safety standards

Safety is the primary concern in medical treatment, safety of patients and practitioners alike. Formal standards of safety for medication and non-medication treatment modalities are established by ministries or departments of health or other appropriate government authorities. In the absence of formal standards, practitioner organizations should establish such standards. The WHO guidelines on evaluation of traditional medicines used for the treatment of malaria, HIV/AIDS, diabetes, hypertension and sickle-cell anaemia, and other WHO documents, should be used for this purpose [14, 15]. Published literature may also serve as guidelines in the absence of government or professional organization standards.

Expected outcome	Indicators
Safety standards which assure patient's right to safe medical treatment established or strengthened	Development of guidelines for evaluation of safety, efficacy and quality of traditional medicines
	Usage of WHO guidelines for evaluation of safety, efficacy and quality of traditional medicines
	Publications of notices serve as indicators of safe practices

### Promotion of the proper use of traditional medicine modalities

The effectiveness and safety of a traditional medical practice, with or without the administration of medicaments, can best be determined by investigators in academic and research institutions, ministries or departments of health and other research organizations. The outcome will impact on all segments of society, including the patient and the practitioner. These studies are costly, and funding may be required from the public sector, private sector and nongovernmental agencies.

Expected outcomes	Indicators
The use of safe and effective traditional medical treatments promoted	The adoption of safety standards and guidelines by ministries or departments of health;
Consumers take charge of their health because of government-sponsored promotional activities on rational medicine use	Publication of scientific literature
	Advocacy on the proper use of traditional medicine in scientific forums

### Local production of traditional medicines

The policy on traditional medicine should make provisions for the development of local production of traditional medicines for which evidence of safety, efficacy and quality has been determined. Such medicines should be included in the national list of essential medicines. Provision of such mechanisms may include the development of improvement of local production of traditional medicines; encouragement to local industry to invest in the cultivation of medicinal plants; creation of an enabling political, economic and regulatory environment for local production; and large-scale cultivation and conservation of medicinal plants.

Expected outcomes	Indicators
Creation of an enabling political, economic and regulatory environment for large-scale local production, large-scale	Development of policy which includes local production of traditional medicines, cultivation and conservation of medicinal plants cultivation and conservation of medicinal plants
Traditional medicines included in a national essential medicines list or an approved list for traditional medicines	A list of traditional medicines to be used for common health conditions

## Partnerships

Partnerships between conventional and traditional medicine practitioners in areas such as referral of patients, research and information exchange at local level should be emphasized. An evidence-based treatment approach will minimize bias, and is very important in promoting and effecting harmonization. Conventional health practitioners need adequate education and awareness of the practice, principles and context of traditional medicine. Similarly, traditional health practitioners need to be more aware of the nature of practice and strengths of modern medical approaches in order to promote the best care of patients. Improved access to information, generation of information through appropriate research, better education and training, and cross-practice collaboration are also factors for fostering partnerships.

Expected outcomes	Indicators
Mutual respect and benefit-sharing between traditional and conventional health practitioners	Sharing of information
Deeper understanding of traditional medicine by conventional health practitioners	Referral of patients
Agreements on benefit-sharing between traditional and conventional health practitioners	Joint research projects, meetings, workshops and seminars

## Technical cooperation

The importance and benefits of technical cooperation with other countries should be emphasized. Mechanisms to facilitate this cooperation should be included in the policy.

Expected outcomes	Indicators
Capacity building in research and training of personnel	Networking of institutions conducting traditional medicine research and institutions teaching traditional medicine
Knowledge and experiences on traditional medicine and research shared among countries	Exchange of information, training and research personnel

### Monitoring and evaluation

A process for monitoring and evaluation of the progress and success of the policy on traditional medicine should be clearly defined and established. The indicators for monitoring and evaluation of each component of a national policy on traditional medicine have been outlined in phase 3 (policy implementation) and phase 4 (monitoring and evaluation), above.

## Part II :

# Model Legal Framework For The Practice of Traditional Medicine: A Traditional Health Practitioners Bill

## 2.1 INTRODUCTION

The Model Traditional Health Practitioners Bill is exactly what it says it is: a model. In other words, as a regional framework, it sets out broad suggestions for developing a legislative tool at country level to govern traditional medicine.

One of the principles of the Regional Strategy on Traditional Medicine is government recognition. This calls for the development of a legal framework which will address the issue of charlatans. This Bill therefore, is a legal framework or a regulatory tool for the practice of traditional medicine in countries of the WHO African Region. The framework provides for the establishment of Traditional Health Practitioners Councils; regulatory frameworks to ensure the efficacy, safety and quality of traditional health care services provided by THPs; and control over the registration, training and practice of THPs.

It is expected that this system of registering and licensing only those THPs who are accredited would drastically reduce the number of charlatans. This regulatory tool will assist Member States to enact laws to govern the practice of traditional medicine. It is meant to fill the vacuum that obviously exists in the availability of generic tools and should guide countries striving to produce national legal document for the regulation of traditional medicine activities. To that end, it is expected that the countries will adapt this Bill according to their own situation and establish a Traditional Health Practitioners Council, Board or Committee which will control over the registration, training and practice of THPs.

In preparing this regional legal framework, due account has been taken of country specificities especially as regards differences in economic, sociocultural, religious, legal and political contexts. Also notable are the major differences that exist in the level of development of traditional medicine and the availability of resources in the various countries. These country specificities impose a strong limitation on any attempt to go into specifics in setting out the provisions contained in this Bill. As a result, the provisions of the Bill are limited to broad outlines, going into detail only when the overall context permits. That is why, for practicality, this regional framework is meant to be adapted to the specific context of each country.

Also worth noting is the emphasis that this legal framework places on the establishment of the Traditional Health Practitioners Council or similar body and the development of its operating procedures. That is in recognition of the pivotal role assigned to the Council in the general oversight of the activities of THPs. Whereas the Model Codes of Ethics and Practice focuses primarily on the Traditional Health Practitioners Association as well as the Professional Ethics Committee, the thrust of the Bill is on the Council which is the principal body in charge of the day-to-day regulation of traditional medicine activities at country level.

Specifically, the Bill seeks to provide for the establishment and organization of a traditional health practitioners council or a similar body; define the functions of the THPs Council; provide for the registration and licensing of THPs (including traditional birth attendants) by the Council; and regulate the preparation and sale of herbal medicines.

## 2.2 STRUCTURE OF THE MODEL LEGAL FRAMEWORK

The model framework presented here has six sections. For purposes of discussion and easy (legal) reference, the paragraphs are numbered.

### SECTION 1: PURPOSE AND DEFINITIONS

#### Purpose

1. There shall be enacted a Bill setting up a Traditional Health Practitioners Council (in some countries the Council is called Board or Committee) to regulate the practice of traditional medicine. This Bill which may be called the Traditional Health Practitioners Bill shall come into operation on such date and such time to be determined by the Minister of Health or appropriate national competent authority by statutory instrument.

#### Definitions

2. In this Bill, unless the context otherwise requires:

*Association* means an association or body of associations of traditional health practitioners recognized by the Minister of Health.

*Certificate of competence* means a certificate issued to a person who has passed an examination set by the Council.

*Chairman* means the Chairperson of the Council.

*Council* means the Traditional Health Practitioners Council or a similar body established to regulate the practice of traditional medicine in the country.

*Herbal medicine* means a plant-derived material or preparation with therapeutic or other human health benefits which contains either raw or processed ingredients from one or more plants. In some societies, materials of inorganic or animal origin may also be used in preparing herbal medicine.

*Improper conduct* or *misconduct* means any conduct which, in regard to the practice of traditional health professionals, is improper or disgraceful, whether or not defined in the Bill or in bye-laws.

*Member* means a member of the Council.

*National competent authority* means any Minister whom the Head of State has assigned to be responsible for the administration of this Bill

*Practice* means the practice of traditional medicine.

*Practitioner* means a traditional health practitioner who uses herbs and other natural products in his/her practice.

*Premises* means any facility where traditional medicine is practised.

*Prima facie* means first hearing.

*Profession* means a calling as a traditional health practitioner.

*Registered* means registered in the Registry of Traditional Health Practitioners as provided in this Bill.

*Registry* means the Registry of Traditional Health Practitioners referred to in this Bill.

*Registrar* means the Registrar of the Traditional Health Practitioners Council referred to in this Bill.

*Traditional medicine* means the total combination of knowledge and practices, whether explicable or not, used in diagnosing, preventing or eliminating a physical, mental or social imbalance and relying on practical experience and observations handed down from generation to generation, whether verbally or in writing [1].

*Traditional health practitioner* is a person recognized by the community as competent to provide health care, using vegetable, animal or mineral substances and certain other methods, based on the sociocultural and religious background as well as on the knowledge, attitudes and beliefs that are prevalent in the community regarding physical, mental and social well-being and the causes of disease and disability [16].

*Vice-Chairman* means the Vice-Chairperson of the Council.

## **SECTION 2: TRADITIONAL HEALTH PRACTITIONERS COUNCIL**

### **Establishment and functions of the Council [17, 18, 19]**

3. There shall be hereby established a body corporate known as the Traditional Health Practitioners Council referred to in this Bill as *the Council*. The Council shall have perpetual succession, a common seal and may sue or be sued in its own name, and with power, subject to the provisions of this Bill, to do all such things as a body corporate may by law do or perform.
4. The Council shall, in this regard, and to the extent possible:
  - (a) issue certificates of registration and licences to qualified traditional health practitioners and shall license premises for the practice of traditional medicine;
  - (b) set standards for the practice of traditional medicine;
  - (c) formulate and enforce a code of ethics for traditional medicine practice in conjunction with an association of traditional health practitioners recognized by the Minister of Health and referred to in this Bill as *the Association*;

- (d) advise the national health authority on matters relating to and affecting the practice of traditional medicine;
- (e) collaborate with the national drug regulatory authority on rules for the registration, advertisement, manufacture, packaging, preparation, labelling, sale, supply, exportation and importation of any herbal medicine;
- (f) determine the curricula required for education and training in traditional medicine at different levels in consultation with associations of traditional health practitioners and educational institutions;
- (g) advise educational institutions on the curriculum for training in traditional medicine in the institutions;
- (h) promote and support education, training and research in traditional medicine;
- (i) promote the practice of traditional health practitioners and develop educational and training methods for them;
- (j) collaborate with the appropriate agencies for large-scale cultivation of medicinal plants and for the preservation of biodiversity;
- (k) promote the practice of traditional health practitioners, foster research into, and develop knowledge of, such practice;
- (l) make grants or loans to associations or persons where the Council considers this necessary or desirable for, or incidental to, the attainment of the purposes of the Council;
- (m) perform such other functions as are ancillary to the objectives of the Council or assigned by the Minister.

### **Ministerial responsibility and directives**

5. The Minister shall have ministerial responsibility over the Council and may give to the Council such directives as to general matters of policy to be followed by the Council in the performance of its functions.

### **Composition of the Council**

6. The membership of the Council shall include, but not be limited to, long-serving traditional health practitioners, representatives of the Traditional Medicine Units or services (where applicable), the medical association, the association of pharmacists, anthropologists, the association of nurses, the universities, research institutions and the national drug regulatory authority. The composition of the Council shall be such that 55% of its members are traditional health practitioners while the remaining 45% shall be drawn from the stakeholders indicated above. The Chairman of the Council shall be a traditional health practitioner. All the members shall be appointed by the minister, upon nomination by the appropriate professional bodies. The Council shall elect its Vice-Chairman and appoint its Registrar.

## Registrar

7. The Minister shall, upon consultation with the Council, appoint a person to be a Registrar of the Council. The functions of the Registrar shall be to act as secretary to the Council. In this connection, the Registrar shall, on receipt of instructions from the Chairman of the Council, convene meetings of the Council and of any committee thereof and be responsible for the proceedings and record keeping of such meetings. Furthermore, the Registrar shall carry out any other duties assigned to him under the provisions of this Bill or existing bye-laws or by the Council.

## Tenure of office of members and vacancies

8. Matters concerning the tenure of office of members of the Council and vacancies of Council posts shall be set forth in the national bill or related bye-laws specifying the duration of tenure preferably not exceeding three (3) years, the maximum number of consecutive terms, the procedures of resignation, the conditions of suspension or removal from office etc.

## Filling of casual vacancy

9. Whenever the office of a member becomes vacant before the expiry of the stipulated term of office, the Minister may appoint another person to fill the vacant office only for the unexpired term of office of the person being replaced.

## Meetings and decisions of the Council

10. The Council shall hold its first meeting on such date and at such place as the Minister may determine. Thereafter, the Council shall meet as often as it deems fit for the dispatch of its business, adjourn, close and otherwise regulate its meetings and procedures as it thinks fit. It shall present a report setting out the activities of the Council since the previous year.
11. Special meetings of the Council may be convened by the Chairman of the Council at any time on the Chairman's own initiative or by the Chairman within twenty-one (21) days of receipt of a request in writing signed by not less than one-third of the members of the Council, specifying the purpose(s) for which the meeting is to be convened.
12. The Chairman or (if absent) the Vice-Chairman shall preside over all meetings of the Council. In the absence of both the Chairman and Vice-Chairman the members present at a meeting shall elect one of their members to preside over the meeting.
13. At least one-third of the membership of the Council is needed to form a quorum at any of its meetings. All acts, matters or actions authorized or required to be taken or addressed by the Council shall be decided by a majority vote at a valid meeting of the Council, i.e. a meeting at which a quorum is attained.
14. At all valid meetings of the Council each member present shall have one vote on a question before the Council and, in the event of equal votes, the person presiding over the meeting shall have, in addition to a deliberative vote, a second or casting vote.

15. On any special occasion, if the Council desires to obtain the advice of any person on any particular matter, the Council may co-opt that person to be a member for as many meetings as may be necessary, and that person, while so co-opted, shall have all the rights and privileges of being a member, except that the person shall not vote on any matter to be decided upon by the Council.
16. The proceedings of the valid Council meeting shall not be invalidated by reason of a vacancy among the members or a defect in the appointment or qualification of a member, or any such considerations.

### **Establishment and appointment of committees of the Council**

17. The Council may establish committees consisting of members of the Council or non-members to exercise any of its functions.

### **Regional and district branches of the Council**

18. For the purpose of effectiveness, and to reach out more easily to the remotest parts of the country, the Council may establish in each regional capital and in such districts as the Council may determine, regional and district offices of the Council. The functions of such decentralized offices shall be governed by the provisions of this Bill and such bye-laws as are applicable to this purpose.

### **Allowances**

19. There shall be paid to the members of the Council, members of a committee of the Council or persons co-opted to attend meetings of the Council, such travelling and other allowances as may be approved by the Minister of Health in consultation with the appropriate authority, including the Minister for Finance.

### **Annual report and other reports**

20. The Council shall, as soon as practicable after the expiration of each financial year, but within six months after the end of the year, submit to the Minister an annual report covering the activities and operations of the Council for the year to which the report relates. The annual report thus submitted shall include an audit report. The Council shall also submit in writing to the Minister such other reports as the Minister may require.
21. The national competent authority shall within two months after the receipt of the annual report submit a report to the appropriate legislative body with such statement as is considered necessary.

## **SECTION 3: REGISTRY OF TRADITIONAL HEALTH PRACTITIONERS**

### **Registry of traditional health practitioners and certificates of registration [17, 19]**

22. The Registrar shall establish a Registry of traditional health practitioners and, in this regard shall: enter in the Register, the name, address and date of first

registration of the traditional health practitioner and such other particulars as the Council may from time to time determine; issue certificates of registration and licensing to practitioners; make any alterations in the name, address or other particulars of a registered and licensed traditional health practitioner; delete from the Register the name of a registered traditional health practitioner who dies, resigns or is suspended or expelled from the association of traditional health practitioners for professional misconduct.

23. When required to do so under the provisions of the Bill, the Registrar shall record in the Registry the registration of a person or, as the case may be, the suspension from practice or expulsion of a registered traditional health practitioner, stating the underlying reasons.

### **Rules regarding the Registry and registration**

24. The Council may make rules concerning the Registry, especially as regards: the manner and form in which applications for registration and licensing shall be made; the information and documents for applications for registration; the form of the Registry and the particulars to be entered therein; the form in which the Registry may be printed and published; the form of the certificate of registration; the issue of duplicate and certified copies of certificates of registration, and certified copies of entries in the Registry; the circumstances and manner in which a person's name may be deleted from the Registry; or in which a person whose name has been removed from the Registry may be reinstated.

### **Offences in connection with the Registry**

25. Any act of unauthorized entry, alteration or deletion from the Registry or a certified copy thereof, or on a certificate of registration; procurement of certificate of registration by fraud, false pretence, or wilful concealment of fact; false declaration or forgery, or any similar acts shall constitute an offence punishable under the provisions of the Bill.

## **SECTION 4: REGISTRATION AND LICENSING OF TRADITIONAL HEALTH PRACTITIONERS AND THEIR PREMISES**

### **Application for registration [17-19]**

26. Subject to the provisions of this Bill, any person who shows to the satisfaction of the Council qualifications as a traditional healer or traditional health practitioner as defined in WHO Technical Report series 622 [20], has treated a required number of patients and has no criminal record shall be eligible for registration as a traditional health practitioner. No traditional health practitioner shall own or operate a practice except if duly registered and licensed to do so.
27. Where the Registrar refuses to register a person as a traditional health practitioner, the Registrar shall inform that person in writing of such refusal and the reasons thereof.

## Council consideration of application for registration and licensing

28. The Council shall consider every application referred to it and, after due inquiry, shall grant the application and direct the Registrar to register the applicant if it is satisfied that the applicant possesses sufficient skills, ability and experience to be registered as a traditional health practitioner and is of good character. On the other hand, the Council shall reserve the right to refuse to recommend the registration and licensing of an applicant if it is not convinced that the applicant meets all the set criteria.
29. The Council, in granting an application for registration, may, where applicable, direct the Registrar to record in the Registry the qualification of the applicant concerned, e.g. as a spirit medium, herbalist, bone setter, traditional birth attendant, etc.

## Appeal against refusal to register

30. Any person aggrieved by a decision of the Council with regard to registration or licensing under this Bill shall have the right to appeal to the Minister. The Minister may, on considering such appeal, confirm or reverse the decision of the Council, vary the decision of the Council, or remit the case to the Council for further consideration.

## Licensing of Premises

31. No traditional health practitioner, citizen or non-citizen, shall operate a practice unless licensed to do so. Applications for a licence for a practice must be sent to the national office or district office of the Council together with a copy of the certificate of registration, a block plan of the premises (where applicable), passport-size photographs of the practitioner, a list of the types of services to be rendered, the prescribed licensing fee, and such other requirements laid down by the Council.
32. Upon receipt of the application, the Council shall decide on whether the applicant meets the stipulated requirement, and shall notify the applicant, accordingly, of its decision.
33. Licensed practitioners shall display their licence in a conspicuous place on the premises that is accessible to all patients. All licensed practitioners shall give unhindered access at any time to inspectors sent by the Council to ascertain the suitability of the premises for the practice of traditional medicine.
34. Any licensed practitioner who owns or operates premises without licence; uses a premise for services other than those for which it is licensed; obstructs the entry for inspection of authorized inspectors; or perpetuates similar acts shall be guilty of an offence punishable under this Bill.

## Registration of non-citizens

35. In order to promote the transfer of indigenous or other knowledge among countries, a person who is not a citizen of the country of residence shall, upon request, be

temporarily or permanently registered as a practitioner, subject to fulfilment of relevant conditions such as proof of qualification as well as other conditions laid down for the registration and licensing of a practitioner who is a citizen.

36. The foreign THP with a valid work permit and licence from the country of origin must immediately report presence in the country and intent to practise to the Council. The THP should pay all fees required by the Council before practising. There should be a waiting period of six (6) months during which the Council conducts an investigation into the qualifications of the visiting THP. The foreign THP may be required to sit for an examination or face an interview panel, or both, before being eligible to practise in the country. The Council has the right to refuse any visiting THP to practise in the country.

### **Renewal of certificate of registration**

37. The certificate of registration shall expire after a stipulated period, as specified by the national competent authority preferably 12 months, and shall be renewable, subject to fulfilment of the laid-down conditions, including a record of satisfactory practice in the past year.

### **Suspension of registration**

38. The Council may suspend, for such period as it may determine, the registration of a practitioner when the Council is investigating an allegation of misconduct on the part of the practitioner or a contravention of any provision of this Bill or of existing bye-laws by the practitioner.

### **Offence**

39. Any action contrary to the Code of Ethics for the practice of traditional medicine shall be deemed as an offence punishable under the Bill.

### **Disciplinary action**

40. The Council shall set up a disciplinary committee or a similar body to make recommendations to the Council on all matters pertaining to disciplinary action against traditional health practitioners. Entities from which members of the Disciplinary Committee shall be selected include, but shall not be limited to, the Council, the Association, and the national drug regulatory authority. Membership on the Disciplinary Committee shall include at least one legal practitioner.
41. Disciplinary action shall be warranted in all cases of proven improper conduct or misconduct in the discharge of functions by a Council member or a traditional health practitioner. Cases requiring disciplinary action shall first be investigated by the Disciplinary Committee which, if it deems appropriate, shall refer the matter to the Council. The Council shall then consider appropriate disciplinary action for the THP concerned.

42. Depending on the gravity of the offence, disciplinary action shall include, but not be limited to, a fine, censure, deletion of name from the Registry, or, where warranted, recommendation for court action.

### **Representation to the Council**

43. No registration shall be cancelled or suspended unless the Council has given the practitioner at least 30 days notice of its intention to suspend or cancel registration and has provided the practitioner an opportunity to make representations, if any, to the Council.

## **SECTION 5: FINANCIAL AND OTHER PROVISIONS**

### **Funds of the Council [17-19]**

44. Any expenses incurred by the Council in the exercise of its functions or the attainment of its purposes in terms of this Bill shall be made from the funds of the Council.
45. The funds of the Council shall consist of such sums as may be appropriated by Government for the Council. Such sums may be paid to the Council as donations, contributions, subscriptions, fees, grants, or gifts, except that the Council shall not raise money from outside the country without the prior approval of the national competent authority. Such other moneys or assets may accrue to, or vest in, the Council as a result of investments made, or transactions entered into, in the course of its operations.
46. The Council shall keep or cause to be kept full and correct records of account of all monies received and expended by it as well as of other records relating to its accounts. It may invest its funds in such manner and to such extent as it considers appropriate.

### **Annual financial report**

47. The Council shall keep books of accounts and proper records in relation to them. The accounts and records of the Council shall be in a form approved by the Auditor-General or similar authority.
48. The accounts of the Council shall be audited by the Auditor-General or similar authority within a specified period after the end of each financial year and a report submitted within a prescribed period to the national competent authority.
49. The Council shall, at the end of each year, and not later than three (3) months after the end of the year, submit to the national competent authority a report of its activities during the previous year, providing such other information as the national competent authority may direct. The annual report of the Council shall, among other things, include a report on the financial affairs of the Council.
50. There shall be appended to the report referred to above an audited balance sheet, an audited statement of income and expenditure during the year, and an audit report on the accounts.

## SECTION 6: MISCELLANEOUS [17-19]

### Approval of rules

51. No rules made by the Council under this Bill shall have the force of law until they are approved by the national competent authority.

### Notification of *prima facie* evidence of improper conduct in a professional respect

52. Whenever, in the course of any proceedings before any court in the country, it appears to the court that there is *prima facie* evidence that a registered person has been guilty of improper conduct in any professional respect, the Court shall cause a copy of the record of such proceedings, or of such relevant portions thereof to be transmitted to the Registrar for information and record purposes, and for appropriate action by the Council.

### Regulation of fees chargeable by traditional health practitioners

53. The Council may, by rules made by it, regulate the fees to be paid by patients to a THP. In determining the applicable fees for various treatments, due regard shall be given not only to the need for affordability but also the need to provide reasonable financial incentives for the practitioners.

### Establishment of ethical codes

54. The Council shall, by rules made by it, establish a code of ethics and a code of conduct for traditional health practitioners.

### Training of traditional health practitioners

55. The Council shall promote the training of traditional health practitioners and shall, in that respect, advise the national competent authority on all matters relating to the standards, curricula and outcomes of the training of traditional health practitioners.
56. The Council may also address issues such as training requirements, conditions for the award of certificate of competence or continuing education programme as deemed necessary.

### Intellectual property rights and indigenous knowledge

57. Nothing in the execution of this Bill shall prevent traditional health practitioners from individually or collectively protecting their intellectual property rights and indigenous knowledge relating to the processing of their medicinal preparations or final products providing always that they shall be entitled to sign an agreement of disclosure in any collaborative works as appropriate.

## Medicines used by traditional health practitioners

58. The traditional medicines used by traditional health practitioners shall meet the requirements laid down from time to time by the Council acting in consultation with the national drug regulatory authority. The Association and the Council shall, in consultation with the national drug regulatory authority, put in place such mechanisms as are necessary to help monitor adherence to such laid-down requirements, and thereby regulate the preparation and sale of herbal medicines. Appropriate protocol, such as those developed by WHO for the evaluation of the quality, safety and efficacy of herbal medicines, is an important tool that countries shall use to this end.

## Regulations

59. The national competent authority, acting in consultation with the Council and the Minister of Justice, may establish regulations for better enforcement of the provisions of this Bill.

## Bye-Laws

60. The Council may make bye-laws prescribing all matters which, by this Bill, are required or permitted to be prescribed or which, in the opinion of the Council, are necessary or convenient to be prescribed for carrying out or giving effect to the provisions of this Bill or the regulation of the practice of traditional health practitioners.

## Amendment

61. A two-thirds majority of the full Council can recommend, through the Minister, amendment to this Bill, for government consideration and approval.

## Commencement of this Bill

62. The provisions of this Bill shall become effective one year after its enactment.

## Part III : Model Codes of Ethics And Practice For Traditional Health Practitioners

### 3.1 INTRODUCTION

The Alma-Ata Conference of 1978 recommended *inter alia*, “that governments give high priority to the full utilization of human resources by defining the role, supportive skills, and attitude required of each category of health workers according to the functions that need to be carried out to ensure effective primary health care (PHC), and by developing teams composed of community health workers, other developmental workers, intermediate personnel, nurses, midwives, physician, and, where applicable, traditional health practitioners (THPs) and traditional birth attendants or (TBAs)” [17]. This recommendation sets forth a clear mandate for governments to define the role THPs and TBAs can play in communities as members of the PHC team. In order to effectively integrate THPs and TBAs into PHC there is need to institutionalize traditional medicine through the development of national policies and establishment of legislation for the practice of traditional medicine.

Despite this policy orientation, governments must make efforts to restrict the practice of traditional medicine to qualified practitioners who are legally accredited as qualified, hence registered and licensed to practise. Registration requirements may differ from country to country. However, apart from the need to possess indigenous and traditional knowledge, experience, and reputation in the communities where they live, THPs should also fulfil other basic requirements as provided for in the rules and regulations of their respective countries. In return, governments should expect THPs to act according to the norms of professional practice and to fulfil their professional obligations, faithfully and honourably, giving due consideration to the well-being of society. The practice of traditional medicine should be governed and regulated by the appropriate laws of the country concerned.

Situation analyses undertaken in 1999 [1] and 2002 [21] by the Traditional Medicine Programme, WHO Regional Office for Africa, and other information from Member States, show that most of the countries in the African Region are having difficulties in institutionalizing traditional medicine as part of their national health policies and legislation. Some of the causes of the difficulties are failure to establish structures and develop codes of ethics and practice for traditional medicine, non-existence of associations of traditional health practitioners; and lack of close collaboration between the practitioners of traditional medicine and those of conventional medicine.

### 3.2 STRUCTURE

This chapter discusses the objectives of a code of ethics and explains relevant terminologies for an understanding of the basic foundation of ethical behaviour governing the conduct of THPs, based on moral values and professional principles in relation to their job, the patient, the public and other practitioners. It provides sample contents of a code of ethics. This is followed by a code of practice which outlines the rules of conduct governing the relationships between THPs and their clients and colleagues in performing duties within their area of competence. The next section addresses disciplinary procedures, and this is followed by the minimum standards for the practice of THPs.

### 3.3 OBJECTIVES AND DEFINITIONS

#### The main objectives of this document are to:

- (a) ensure high standard of conduct and practice among traditional health practitioners;
- (b) foster good relationships among traditional health practitioners, patients and other practitioners;
- (c) increase traditional health practitioners' awareness of the existing rules and regulations governing the practice of traditional medicine.

#### Definitions

The definitions related to traditional medicine can be found in the WHO publication, *General guidelines for methodologies on research and evaluation of traditional medicine* [14].

*Code of Ethics* is a set of rules governing conduct based on moral values which are stated by a recognized professional association.

*Code of Practice* is a written set of rules governing how traditional health practitioners should behave in their practice.

*Ethics* is the science of moral values. The basic foundation of ethical behaviour is the basic precept, "Do good and avoid evil". Ethics, especially professional ethics, attempts to achieve its purpose in the context of this document, through the voluntary self-discipline of THPs.

*Etiquette* denotes the principles and laws of courtesy observed among members of the same profession. It is therefore confined to the rules of conduct governing the relationship among members of an association of THPs.

*Final hearing* means the date, time and place proposed for final consideration by the Professional Ethics Committee of allegations of proscribed conduct.

*First hearing* means the date, time and place proposed for first consideration by the Professional Ethics Committee of allegations of proscribed conduct.

*Herbal medicine* means a plant-derived material or preparation with therapeutic or other human health benefits which contains either raw or processed ingredients from one or more plants. In some societies, materials of inorganic or animal origin may also be used in preparing herbal medicine.

*Medicinal preparations of plant materials* means medicinal preparations that contain one or more of the following: powdered plant materials, extracts and purified active substances isolated from plant materials. In certain cases, materials of animal or mineral origin may also be included in such preparations.

*National competent authority* refers to the authority at local, district, regional or national levels charged with the responsibility of regulating traditional medicine as regards practices, practitioners and products (medicines).

*Processed plant materials* are plant materials treated according to traditional procedures to improve their safety or efficacy, facilitate their clinical use or make medicinal preparations.

*Professional ethics* is the moral principle which should guide members of the Association of Traditional Health Practitioners in their dealings with one another, their patients, patrons, the state etc. An important characteristic that members of the profession should have is a collective and disciplined concern. The attitude of the professional should always be altruistic and selfless concern for the welfare of others.

*Professional Ethics Committee* is a committee consisting of not less than one-third of members of the Traditional Health Practitioners Council appointed by the appropriate national authority so as to ensure a reasonably balanced representation of the membership.

*Proscribed conduct* means dishonourable conduct or professional or ethical misconduct which transgresses the Code of Ethics; and such other acts of misconduct as may reasonably be determined by the appropriate national authority to be professional or ethical misconduct.

*Traditional health practitioner* includes traditional healer, traditional birth attendant or traditional medical practitioner registered with the appropriate national authority, e.g. National Traditional Healers Association, Traditional Medicine Board or similar authority, to practise traditional medicine.

*Traditional medicines* include various products. They are *plant preparations* finished and labelled as medicinal products containing plants and presented as having therapeutic or prophylactic property. They include all preparations partly or wholly containing a plant material. *Animal medicinal products* are finished and labelled medicinal products containing only animal material or their preparations and presented as having therapeutic or prophylactic property. *Mineral medicinal products* are finished and labelled medicinal products, and containing only inorganic material or their preparations. A fourth category includes *preparations or admixtures from herbal, animal or mineral sources* manufactured, sold or advertised for use in the diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical state or the symptom thereof in humans or animals. Finally, preparations or admixtures from herbal, animal or mineral sources are used for restoring, correcting or modifying organic function in humans or animals.

### 3.4 CODE OF ETHICS

Commitment to professional ethical standards starts with the swearing of a professional oath and acceptance of the professional Code of Ethics. The oath is usually brief, general and intended to oblige and inspire a member to abide by applicable laws, codified ethics and the dictates of conscience and religious principles.

The examples below are adapted from specific country codes of ethics and practice [22-23]. It is understood that the appropriate national authorities shall reserve the right to revise the provisions of these codes of ethics from time to time.

## Traditional Health Practitioners in Relation to Their Job

Individual members of the Traditional Health Practitioners Association shall, at all times, conduct themselves in an honourable manner in their relationship with their patients, the public and other practitioners.

Traditional health practitioners shall:

**Article 1.** As a matter of primary concern, promote the health and well-being of the patient and the general public. The traditional health practitioner shall refrain from any act that may adversely affect the patient's health.

**Article 2.** Practice traditional medicine only after having been formally registered to do so.

**Article 3.** Provide comprehensive services in their profession.

**Article 4.** Desist from delegating personal tasks to a subordinate or assistant. In the event of such delegation, the practitioner should provide the necessary guidance and supervision and will be held liable in case of negligence.

**Article 5.** Immediately report to the appropriate authority any observed undesirable reactions and side effects noted in the cause of the treatment.

**Article 6.** Not use allopathic medicines as adulterants.

**Article 7.** Limit their interventions and practice to the areas of their competence and refer to an appropriate authority all cases beyond their competence.

**Article 8.** Update their knowledge and maintain professional competence directly related to their specific areas of practice.

**Article 9.** Provide information on traditional medicine to the public as well as to other health professionals when necessary.

## Traditional Health Practitioners in Relation to Their Patients

Traditional health practitioners shall, in dealing with their patients:

**Article 1.** Show a high sense of integrity at all times in their interaction with their patients.

**Article 2.** Inform their patients about the procedures involved in the treatment, which they intend to administer.

**Article 3.** Respect the right of a patient who either accepts or refuses treatment by traditional medicine (except if the law requires such treatment of the disease).

**Article 4.** Refrain from abusive use of that relationship for personal gains.

**Article 5.** Refrain from any act(s) of discrimination towards patients. In this respect, they shall not discriminate between patients on the grounds of age, nationality, creed, colour, religion, sex, social status, political affiliation etc.

**Article 6.** Give appropriate advice to the patient, the patient's family and the community for purposes of disease prevention, care (including home-based care), and management and health promotion in the context of primary health care.

**Article 7.** Provide all the necessary information and guidance on the proper use of traditional medicines.

**Article 8.** Keep clear and comprehensive records of all patients treated in their practice.

**Article 9.** Be considerate in matters concerning fees or remuneration and justification for treatment.

**Article 10.** Keep all information and views formed about patients entirely confidential, except if:

- (a) Disclosure is clearly and justifiably in the patient's interest, or
- (b) There is a need for disclosure, e.g. when the practitioner considers referral necessary, when disclosure is mandatory by law.

**Article 11.** Not disclose confidential information to a patient's spouse or any other person, except if authorized to do so by the appropriate authority.

### **Traditional Health Practitioners in Relation to Their Colleagues**

Traditional health practitioners, in maintaining good professional relations with their colleagues, shall:

**Article 1.** Support, respect and cooperate with fellow practitioners in addressing needs for scientific and technical information.

**Article 2.** Regard other members of the Traditional Health Practitioners Association as colleagues and always appreciate the need for referral of cases which they cannot manage to a specialist more competent in treating that particular type of ailment.

**Article 3.** Adhere to procedures laid down by the appropriate national authority when referring patients or dealing with patients referred to them by other practitioners.

**Article 4.** Not express their opinion of a colleague's competence or conduct to a third party, especially a patient, as this is deemed unprofessional and unethical.

**Article 5.** Report to the appropriate authority any act(s) of misconduct or malpractice by a fellow traditional health practitioner in order to uphold the honour and integrity of the profession and thereby contribute to the enforcement of the law.

**Article 6.** Participate in the activities of their own professional associations and of other associations or organizations with the objectives of promoting traditional medicine.

**Article 7.** Not express undue alarm or show any such reaction upon receiving a patient who has been improperly treated or referred by another traditional health practitioner.

**Article 8.** Refrain from making comments that undermine the integrity of colleagues.

**Article 9.** Not make any secret arrangement or negotiations with a health practitioner for offers, commission etc, in return for favours in patronage, referral, etc.

**Article 10.** Not connive with other traditional health practitioners to engage in any malpractice(s).

**Article 11.** Strive for the promotion of health, expansion of health service and the development of team work spirit with other traditional health practitioners.

## **Traditional Health Practitioners in Relation to the Public**

Traditional health practitioners, in relation to the public, shall:

**Article 1.** Refrain from using the title “Doctor”, either directly or indirectly, in a way likely to suggest that they are registered conventional or orthodox medical practitioners, except if that is the case. The use of the title “Doctor” could be misleading to the public. Any community may decide on a title which is acceptable by the community to identify the traditional health practitioner.

**Article 2.** Not use, carry or possess a stethoscope or any such equipment normally used by only qualified conventional medical practitioners or dentists, except if the traditional health practitioner is a qualified and licensed medical practitioner.

**Article 3.** Not administer an anaesthetic, or an injection, whether by subcutaneous, intramuscular, intravenous or any other route; except if the traditional health practitioner is a qualified and licensed medical practitioner.

**Article 4.** Not use surgical procedures to facilitate the examination of any person, except if the traditional health practitioner is a qualified and licensed medical practitioner.

**Article 5.** Immediately report all deaths on the premises to the police for record purposes.

**Article 6.** Report all births to the appropriate authority.

**Article 7.** Subject to the requirements of the law, observe strict confidentiality as regards the patient’s disease(s), the types of traditional medicine used or any such information that patients may disclose to them in the course of consultation.

**Article 8.** Keep information such as the patient’s history and other records under strict secrecy except as otherwise required by law or for purposes of settlement of financial reimbursement. This secrecy shall be exercised in regard to all other confidential information in their possession.

**Article 9.** Be accountable and liable in the situation of damage inflicted on the patient as a result of negligence or non-compliance in the discharge of their professional duties; negligence or professional misconduct; failure to report undue obstruction of their duties by an unauthorized person(s).

**Article 10.** In the conduct of research on the evaluation of the safety, efficacy or quality of traditional medicines on humans in collaboration with scientists or institutions, participate in

such joint experiments involving human subjects only when all the ethical standards are fulfilled. Each experiment should receive prior ethical clearance and approval by the appropriate authority, as well as the written consent of the subject.

**Article 11.** Immediately report, to the principal investigator of the research team, any adverse findings, especially when the health or well-being of the subject is in danger.

**Article 12.** As responsible members of society, be law-abiding and strictly adhere to the laws of the country as well as socially accepted norms; keep their honour and maintain high standards of integrity in the community where they live; promote and show concern for social justice in the community; be enlightened and conversant with the laws in every aspect of their professional practice.

**Article 13.** Not prescribe any medicines made from or containing parts of the human body or organs.

### Traditional Health Practitioners in Relation to Sexual Abuse of Minors

Minors should not be involved in traditional practices in any manner that will lead to their involvement in sexual activity. The appropriate authorities should therefore prohibit any prescriptions or practices carried out in the name of traditional medicine, but leading to the involvement of minors in sexual activity. The appropriate authorities should, in this respect, clearly spell out in the code of practice for traditional health practitioners, the responsibilities of these practitioners to protect minors, especially young girls, from sexual abuse.

Breach of this section of the code should warrant adequate disciplinary action by the appropriate authority e.g. expulsion from the membership of registered traditional health practitioners, as well as indictment for indecent assault, incitement to commit a sexual offence, etc. Any traditional health practitioner found to be in breach of this section of the code must be reported to law enforcement agents and the disciplinary authorities for appropriate action.

Traditional health practitioners, in dealing with minors, shall:

**Article 1.** On no account, prescribe or administer sexual activity as a form of treatment of any ailment whatsoever, physical or spiritual. They shall not, in the course of treatment, request or require a client to undress or be exposed in a manner deemed to be indecent.

### Management and Ethical Utilization of Traditional Medicines

Traditional health practitioners shall:

**Article 1.** At all times, in the course of advertising, abide by the rules that shall be laid down by the appropriate authority from time to time. Advertising, both in its form and content, shall aim to protect the interest of patients.

**Article 2.** Refrain from any act(s) purported to denigrate other traditional health practitioners or other professions.

**Article 3.** Refrain from falsehood, and from making fraudulent, misleading, deceptive, self-laudatory, extravagant or unduly sensational claims.

**Article 4.** Adhere to the legal requirements and to the provisions of the national code of advertising.

**Article 5.** Not display materials likely to bring the profession into disrepute and refrain from making false promises to cure diseases.

**Article 6.** Be subject to disciplinary action for contravening the national regulations, if they belong to more than one association and do not adhere to regulations of such associations, thinking that their dual or multiple memberships gives them immunity.

**Article 7.** Be held personally accountable for professional misconduct by their staff or assistants who are not registered with the appropriate national authority but are practising under their supervision.

**Article 8.** Be liable to disciplinary action with possible loss of the privileges and benefits of registration with the Traditional Health Practitioners Association upon infringement of the Code of Ethics.

**Article 9.** Not make available for sale or dispense to patients, traditional medicines that are substandard, mislabelled or adulterated.

### 3.5 MODEL CODE OF PRACTICE

Traditional health practitioners shall comply at all times with the requirements of the Code of Practice. Any traditional health practitioner who fails to meet the requirements of the Code of Practice shall be held in breach of the Code of Ethics and shall be subjected to disciplinary measures on the grounds of professional misconduct.

#### Premises and location of practice

In keeping with the Code of Practice, traditional health practitioners shall:

**Article 1.** Carry out their practice in properly registered building(s) or premises as specified in their licence(s).

**Article 2.** Ensure that the building is clean and tidy. If only a part of the building is used for traditional medicine practice, the part so used must be clearly demarcated from the part used for other purposes, in order to ensure the privacy and cleanliness of the clinic. Adequate arrangements must be made for refuse collection and disposal as well as the general upkeep of the premises.

**Article 3.** Not practise in any district or area other than that specified in their licence(s) without the consent, in writing, of the appropriate authority.

#### Application for Licence

The traditional health practitioner shall:

**Article 1.** Address the request for application for a licence, or for renewal of a licence, to practise as a traditional health practitioner to the appropriate authority in the form prescribed by the authority and shall contain such particulars as are required by the relevant rules.

**Article 2.** Whenever changing address, shall notify the appropriate authority of such change within a specified period, failure of which shall constitute an offence.

**Article 3.** Not deliberately furnish false information, or information that is misleading, when applying for a licence; providing any misinformation shall be guilty of an offence.

**Article 4.** Obtain a licence to practise traditional medicine in the form prescribed by the appropriate authority.

### Areas of Competence

Traditional health practitioners shall:

**Article 1.** Work strictly within the areas(s) of competence for which they have been registered by the appropriate authority.

**Article 2.** Not perform an abortion when it is illegal and shall not administer an abortifacient or known uterine muscle stimulant remedies to a pregnant patient. Furthermore, they shall not administer any instrument meant to induce abortion or assist in any such illegal operation.

### Patient Examination and Treatment

Traditional health practitioners shall:

**Article 1.** Conduct intimate examination of a patient of the opposite sex only in the presence of a relative of the patient or an assistant of the same sex as the patient.

**Article 2.** Treat or examine a child under the age of 18 only in the presence of a parent, supervising adult or an assistant of the same sex as the child.

### Fees

**Article 1.** The Traditional Health Practitioners Council may, by the rules made by it, regulate the fees to be paid by patients to a THP. In determining the applicable fees for various treatments, due regard shall be given not only to the need for affordability but also to the need to provide reasonable financial incentives for the practitioners.

### Patient Records and Notifiable Diseases

All traditional health practitioners shall be required to:

**Article 1.** Keep complete and proper records of the name, address, age, sex and ailment of each and every patient, including the prescribed dosage, the name of the medicine dispensed or administered to the patient as well as the dates on which the patient reported for consultation or treatment. Whenever a patient is admitted for a day or more, then the record must include the dates of admission and discharge of the patient. When the traditional health practitioners can neither read nor write, they must engage the services of a literate worker to help keep proper records.

**Article 2.** Notify the health authority of any disease they are treating, which is on the current list of notifiable diseases.

**Article 3.** Upon request, make all records available for inspection by authorized persons.

## Dispensing, Labelling and Administration of Traditional Medicines

Traditional health practitioners shall:

**Article 1.** Comply with the regulations laid down by the appropriate authority as regards the dispensing and labelling of medicines. All medicines should be clearly labelled, specifying the correct dosage, other instructions for use, the name and address of the patient and the date on which the medicine was dispensed. Dates of manufacture and expiry should be included where possible.

**Article 2.** Under no circumstances use or dispense orthodox medicines, whether alone or together with traditional remedies. Such action shall be in contravention of the regulations.

**Article 3.** Not administer traditional remedies by injection with syringes except with the official permission of the appropriate authority.

**Article 4.** Not administer an anaesthetic.

**Article 5.** Not administer an injection, whether by the subcutaneous, intramuscular, intravenous or any other route.

**Article 6.** Not use any surgical procedures to facilitate the examination of any person.

**Article 7.** Report immediately to the appropriate authority any outbreak of illness or diseases involving ten (10) or more persons simultaneously in the area in which they are entitled to practise, which may come to their notice in the course of their practice.

### 3.6 A MODEL FOR DISCIPLINARY PROCEDURES

Disciplinary procedures should be followed by the appropriate national authority in the event of professional or ethical misconduct on the part of a traditional health practitioner.

#### Dishonourable Conduct, Professional and Ethical Misconduct

**Article 1.** All reported cases of professional misconduct on the part of a traditional health practitioner shall be referred to the Professional Ethics Committee (PEC) for necessary action.

**Article 2.** In determining whether an action by a traditional health practitioner amounts to misconduct, consideration shall be given to any directions, advice or statements issued or made by, or on behalf of, the appropriate authority as regards that action whether of a general or specific nature, or of any Code of Ethics or rules adopted by the appropriate authority.

**Article 3.** The Professional Ethics Committee shall serve on the traditional health practitioner concerned written notice of the allegation(s) made against the practitioner, including full details of the complaint received. The PEC shall, in this regard, inform the traditional health practitioner concerned of the first hearing, which shall be not less than 15 days after the date of service of the notice specified in this article.

**Article 4.** The Professional Ethics Committee shall notify the traditional health practitioner concerned of the individual right to submit a full written statement of evidence on own behalf, or a written request to personally give oral evidence on own behalf if desired. In addition, the Professional Ethics Committee shall inform the THP that the statement of evidence referred to in this Article should be in full, and that such statement and/or request of the practitioner concerned must be served on the Professional Ethics Committee within a period specified by the Professional Ethics Committee after service on the practitioner concerned of the notice specified in this Article.

**Article 5.** The Professional Ethics Committee shall accept both oral and written evidence.

**Article 6.** Should the traditional health practitioner concerned fail to serve on the Professional Ethics Committee a statement and/or reply and/or notice in accordance with the relevant articles of the Code of Ethics the Professional Ethics Committee may, after expiry of the time for service specified herein, proceed to the first hearing or the final hearing, respectively, without considering any written evidence which might have been included in such statement and/or reply and/or notice and in the absence of the traditional health practitioner concerned.

**Article 7.** The Professional Ethics Committee may adjourn or postpone (more than once, if necessary) the first hearing or the final hearing, respectively, for such period as it thinks fit, provided that at least 15 days before the new date fixed for such hearing or as specified by the appropriate authority, it serves on the traditional health practitioner concerned written notice of the new date, time and place for such hearing.

**Article 8.** The Professional Ethics Committee shall, at the time and place and on the date notified for the first hearing, or of any duly notified postponement or adjournment thereof, meet to decide whether a case of proscribed conduct has been established against the traditional health practitioner concerned. If it finds that a case has not been established against the traditional health practitioner concerned, the PEC shall dismiss the case. If it finds that a case has been established, which if proved, might lead to the de-registration of the traditional health practitioner concerned, the PEC shall not hear the matter but refer it to the appropriate authority. If it finds that a case has been established, but considers the complaint to be of less serious nature, then it shall have a hearing of the matter, by itself and, if it finds the case proved, it shall:

- (a) censure the traditional health practitioner concerned; and/or
- (b) fine the traditional health practitioner a sum prescribed by the appropriate authority. The amount of the fine shall be paid in full within a specified period, usually not exceeding 28 days or as specified by the appropriate authority.

**Article 9.** The provisions of Article 8, above, shall be without prejudice to the powers of the Professional Ethics Committee to adjourn the first hearing.

**Article 10.** The Professional Ethics Committee shall, not more than 14 days or as specified by the appropriate authority, after the hearing, serve written notice on the traditional health practitioner concerned of its decision and submit a written report to the appropriate national authority. Should the PEC decide to fine the traditional health practitioner concerned, the

fine shall be stated in the written notice in addition to stating the period within which the traditional health practitioner concerned is required to pay the fine. Furthermore, the PEC shall inform the THP of the right to appeal to the appropriate national authority.

**Article 11.** If the traditional health practitioner concerned intends to appeal to the appropriate authority against a fine imposed by the Professional Ethics Committee, the THP shall, not more than 14 days after being notified by the PEC, or as specified by the appropriate authority, send a written notice of intention to appeal. Should the practitioner concerned fail to serve such notice within the stipulated timeframe, the right of appeal shall be lost.

**Article 12.** If the Professional Ethics Committee receives notice of appeal in accordance with the relevant articles of the Code of Ethics, it shall require the Chairman of the PEC to convene a meeting of the Committee of the appropriate authority, and not more than 14 days or as specified by the appropriate authority after so requiring, serve on the practitioner concerned notice of the fact that it has done so.

**Article 13.** Any person about whom a complaint has been made or who has lodged a complaint against a traditional health practitioner or is likely to be called upon to give evidence in any such complaint or who is directly interested in its outcome shall not be eligible to sit on the Professional Ethics Committee or the Committee of the appropriate authority at which such complaint is considered, and no member of the PEC which considers such complaint shall be eligible to sit on the Committee of the appropriate authority in respect of the same complaint.

**Article 14.** The procedure to be followed in serving notices in connection with incidents of proscribed conduct shall be as follows:

- (a) a notice shall be served by the committee of the appropriate authority to any practitioner, either personally or by prepaid first-recorded delivery post, in a letter addressed to the traditional health practitioner at the last registered address;
- (b) a notice sent by post shall be deemed to have being served one month following the date on which the letter containing the notice was posted;
- (c) any notice, requisition or other document to be served on the appropriate authority or on any of its staff shall be sent by first class postal delivery to the registered office of the appropriate authority.

**Article 15.** The Committee appointed by the appropriate national authority shall be vested with all the powers conferred upon it by these Articles in so far as they relate to any disciplinary action to be taken against a traditional health practitioner or the reason thereof.

**Article 16.** The provisions of the THP Bill shall determine the quorum of the Committee appointed by the appropriate authority, when considering a complaint. The Committee may enlist the assistance of a legal assessor who shall be a barrister or a solicitor.

**Article 17.** The traditional health practitioner concerned shall have the inalienable right to be heard by the Committee appointed by the appropriate authority, the THP so desires, whether in person or through legal counsel or solicitor or through a lay representative who must also be a traditional health practitioner. The THP shall have the right to choose to submit a statement in writing.

**Article 18.** The traditional health practitioner concerned may, not less than 7 days (or as specified by the appropriate authority) before the scheduled date of the first hearing or the final hearing (but not an adjourned or postponed first hearing or final hearing), serve on the Professional Ethics Committee or the Committee appointed by the appropriate authority (as the case may be) a request for further time to prepare a case. The PEC or the Committee appointed by the appropriate authority (as the case may be) shall, on receipt of such a request, adjourn or postpone the first hearing or the final hearing respectively for a period of at least 15 days (or as specified by the appropriate authority) from the date of the request for further time, in accordance with the applicable provisions of these articles.

**Article 19.** The Committee appointed by the appropriate authority shall serve on the traditional health practitioner concerned a written notice informing of the date of the final hearing which shall be not less than 15 days (or as specified by the appropriate authority) from the date on which such notice is served, and notifying of the right to submit, either :

- (a) a statement of intent, if any, to be heard in person or to be represented by his/her counsel, solicitor or other representative; or
- (b) a written explanatory statement on own behalf, to be served on the Committee appointed by the appropriate authority not more than 14 days after service on the traditional health practitioner concerned of the notice specified in this article.

**Article 20.** The Committee appointed by the appropriate authority shall, at the scheduled time, place and date of the final hearing or on the duly notified date to which the hearing is postponed or adjourned, meet to decide on the case. In considering the case, any previous findings by a Court of competent jurisdiction or by any other relevant professional tribunal shall be binding on the Committee appointed by the appropriate national authority. After hearing all the evidence presented for and against the traditional health practitioner concerned, the Committee appointed by the appropriate authority shall determine whether the defendant has been guilty of proscribed conduct. If the Committee finds that the practitioner concerned is not guilty of proscribed conduct, it shall dismiss the case. If it finds that the THP is guilty of proscribed conduct, it shall:

- (a) censure the practitioner concerned; and/or
- (b) impose a fine on the practitioner concerned, the sum of which shall be decided by the appropriate authority. The fine shall be paid within a specified period not exceeding 28 days (or as specified by the appropriate authority). Furthermore, the appropriate national authority shall reserve right to expel that practitioner from the Traditional Health Practitioners Association and, if it deems fit, prescribe a period of time during which no application for re-registration shall be considered; and/or
- (c) resolve that the practitioner's registration be cancelled, whereupon the THP shall cease to be a practitioner forthwith, and, if it thinks fit, the Committee appointed by the appropriate authority may prescribe a period of time during which no application for re-registration of the practitioner concerned shall be considered. Nothing herein shall entitle the traditional health practitioner concerned to require the said Committee to re-consider its penal decision.

**Article 21.** The Committee appointed by the appropriate authority shall, not more than 14 days (or as specified by the appropriate authority) after the final hearing, serve a written notice on that traditional health practitioner concerned of its decision, which shall be final and be binding on all parties and shall send a written report thereon to the Chairman of the Professional Ethics Committee.

**Article 22.** The requirements of Article 20 above shall be without prejudice to the power of the Committee appointed by the appropriate authority to adjourn the final hearing.

**Article 23.** It is incumbent upon every traditional health practitioner who has been fined, in accordance with the provisions of Article 20(b) above to pay such fine in full within the stipulated period.

**Article 24.** A person who has been fined and de-registered in accordance with Article 20(b) above or whose registration has been cancelled in accordance with Article 20(c) may apply for re-registration by the Committee appointed by the appropriate national authority, provided that such application is made after the period which has been prescribed in accordance with Articles 20(b) and 20(c).

**Article 25.** The Committee appointed by the appropriate authority shall have the power to take appropriate decision on any matters or procedures relating to proscribed conduct, which are not covered by these articles, subject to approval of that decision by the appropriate authority.

### **3.7 A MODEL FOR MINIMUM STANDARDS FOR TRADITIONAL HEALTH PRACTITIONERS**

#### **Preamble**

The following minimum standards indicated below shall only serve to guide each THPs Council in the establishment of national standards.

#### **Modes of Traditional Health Practice**

In most countries of the African Region, traditional health practitioners carry out the following modes of traditional medicine practice, among others:

- (a) Herbal medicine
- (b) Bone setting
- (c) Traditional birth attendance or midwifery
- (d) Traditional surgery
- (e) Traditional psychiatry
- (f) Divination
- (g) Faith healing
- (h) Metaphysics
- (i) Veterinary services.

## Categories of Traditional Health Practitioners

Traditional health practitioners in countries of the African Region may be classified into the following categories:

- (a) Herbalist
- (b) Traditional bone setter
- (c) Traditional midwife
- (d) Traditional surgeon
- (e) Traditional psychiatrist
- (f) Diviner
- (g) Faith healer
- (h) Traditional metaphysicist.

## Skills and Qualifications of Traditional Health Practitioners

Standards for the practice of traditional medicine in terms of skills and qualifications vary from country to country. Some of them, which countries may wish to consider adopting, include the following:

- (a) The minimum level of education for all traditional health practitioners should be the primary school leaving certificate;
- (b) A traditional health practitioner must be a member of a recognized Traditional Health Practitioners Association in the community where the THP practises;
- (c) Every traditional health practitioner must have successfully undergone the attestation procedure stipulated for registration by the competent national authority.

## Skills Required of Traditional Health Practitioners

The skills required for the practice of traditional medicine also vary from country to country. However, in some countries, the following minimum requirements could apply:

- (a) Each Traditional Health Practitioners Council should determine the skills required for the practising traditional medicine.
- (b) A traditional health practitioner must be able to recognize at least thirty (30) different herbs.
- (c) A general herb seller must be able to recognize at least fifty (50) herbs while those selling herbs for specific ailments must be able to identify a minimum of ten (10) herbs that can be used to treat various ailment(s).
- (d) A traditional health practitioner who administers herbs should be able to submit at least two medicaments prepared and used in practice so that they can be tested for efficacy (patent rights agreements should be signed as appropriate).
- (e) Practitioners who are traditional surgeons should limit themselves to the practice of non-invasive surgery, i.e. surgery not beyond skin deep.

- (f) All traditional health practitioners, regardless of their mode of practice or their skills, must conduct their practice within the limits of the law.

## Good Practices in Traditional Medicine and Quality Assurance

Record keeping and documentation should include:

- (a) Scope of practices
- (b) Effectiveness
- (c) Case management
- (d) Complications resulting from treatment
- (e) Sale of herbs or products within the limits of the law
- (f) Continuing education and experience.

Feasible guidelines for monitoring the standards for the practice of traditional medicine should include:

- (a) Registration and accreditation, evidence of valid registration displayed on practice premises
- (b) Re-certification (if stipulated as a requirement for valid current registration)
- (c) Monitoring of facilities, instruments and practice environment
- (d) Records of drug preparation or surgical operation procedures records
- (e) Records of patient output (quantitative and qualitative).

Herbal remedies should meet the quality, efficacy and safety standards set by the appropriate national authority (for herbal medicines) before they are administered to patients or sold to the public.

## Part IV:

# Guidelines For The Formulation of A National Master Plan For The Development of Traditional Medicine

## 4.1 INTRODUCTION

Until recently the concept of planning for the development of traditional medicine and other complementary systems of health care in many countries was unknown. The development of traditional medicine in various countries was left to evolve without major state intervention in the process. Many countries in the WHO African Region and many developing countries do not have management units or official directorates to deal with traditional medicine.

It is therefore not surprising that most countries do not have strategic policies or plans directing the development of traditional medicine. This has led to a very slow development of the sector. Major challenges remain:

The mode of training is based mainly on inheritance rather than a formal structured training programme. A large body of the knowledge is transmitted through oral tradition which in some cases may lead to loss and distortion in the original traditional knowledge base. A lot of the knowledge is locked up in shrines and sacred places and not exposed and shared with biomedical researchers. There has been poor documentation of knowledge and skills required to practice traditional medicine to the extent that younger generations have no idea of original traditional therapeutic practices. The traditional health care system as an intellectual property of custodians of practitioners has no protection in many countries. As a result, the knowledge base is stolen without adequate compensation to the beneficiaries. There is continuous depletion of medicinal plants, and there is no programme to replace them. Continuous depletion can pose a danger to the ecosystem and the flora and fauna of many countries. Inadequate technological skills in the commercial preparation of traditional medicine products will also lead to poor industrial support for the sector. There has been ineffective regulation, monitoring and evaluation.

The overall result of these problems is the loss of the potential benefits of an efficient and high quality traditional medicine practice to the general population. Therefore, planning for the development of traditional medicine is of paramount importance as it will provide both a policy direction and a set of key priorities that has to be implemented by a nation in an integrated fashion. The national master plan should be developed immediately after a national policy on traditional medicine has been formulated.

## 4.2 STRUCTURE

This chapter consists of three sections. The first section discusses major challenges that some countries are facing in the WHO African Region. These challenges are hindering the establishment of a national management body, a directorate, a focal point or similar structure for coordinating traditional medicine activities. This section also underscores the need for

and conditions under which a national master plan should be developed. The second section addresses issues related to the concept of planning, including the primary steps in the planning process. The third section outlines the recommended steps in the process of preparing the national master plan to ensure that the plan is both technically sound and widely accepted by all key stakeholders.

## 4.3 DEVELOPMENT OF A MASTER PLAN

### Reasons for Planning

Planning involves a systematic analysis of a problem, setting priorities and objectives, and developing a series of actions to be carried out to solve the problem. The process of planning for traditional medicine has often been ignored by government authorities. Budgetary allocations to the traditional medicine sector have been made without regard to dealing with priority problems and activities.

Planning as a management tool has the potential to help people think clearly and systematically about what should be done over a given period of time. Planning can thus give a sense of direction to work. It helps to prioritize activities, set objectives and set targets. It helps in the analysis of the environment that will be operated in and thus offers us an opportunity to implement our programmes effectively. Planning enables the effective use of resources. Planning also offers an opportunity to recognize successes and shortcoming in relation to targets.

Planning can serve to increase participation in decision-making which can lead to an increased commitment to programme implementation; people may be more willing to implement programmes and policies that they have helped to formulate. By facilitating clear definition of roles, planning can help to minimize interpersonal conflicts. A good plan can be a powerful tool for justifying a budget and the best defence against inappropriate top-down decisions.

### The Need for a Master Plan

A master plan for traditional medicine is a document that provides the national agenda for the development of traditional medicine.

A number of institutions in the WHO African Region have a stake in the development of traditional medicine. They all have plans and programmes even though they may not be coordinated. Two or more traditional medicine institutions could carry out the same or similar activities without their managers being aware. This leads to duplication of functions and a waste of scarce resources. It is for these reasons that a master plan is needed.

The master plan first provides a general strategic direction on the development of traditional medicine as a sector. From the master plan, specific institutional plans are derived. The master plan provides both policy direction and a set of key priorities to implement in an integrated fashion.

## Conditions for Developing a Master Plan

For the development of the master plan to be worthwhile and productive, it must take place in an environment that supports the objectives of planning. Various conditions represent fundamental prerequisites to the development of a supportive planning environment. There must be a government coordinating institution, management body or similar authority responsible for traditional medicine in the country. This authority must have the capacity to assume responsibility for developing strategic plans for traditional medicine. It should have the capacity to prepare a master plan, operational plans and budget. There should be a guarantee that the contributors to the plan would be provided with the minimum required financial support to implement planned activities.

The government should be committed to developing traditional medicine as an alternative system of medical practice. Traditional medicine should be viewed as beneficial to health and health services development in the country where policies already exist, or it must be developed together with the master plan.

### Box 2: Some organizations and their role in the development of traditional medicine

Organization	Role
Food and Drugs Board traditional medicine materials	Register food and drugs, including
Research institutions	Research to assess medicinal value of plants; developing TM into a large-scale industry
University departments of pharmacy, biochemistry and botany	Teach TM and related subjects such as pharmacy; conduct research onto plants and their properties (especially medicinal properties)
TM Groups	Apply the knowledge and skills of TM practitioners
Standards Board	Provide standards for dispensing TM products
National Medical Association	Regulate; develop policy
National Medical and Dental Council	Regulate; develop policy
Nurses and Midwives Council	Regulate; develop policy
Pharmacy Council	Regulate; develop policy

## 4.4 THE CONCEPT OF PLANNING

Planning is anticipating the future. It involves assessing present conditions and making decisions about the future direction of programmes and projects and the deployment of resources for the implementation of such programmes and projects. Planning involves determining what is to be done, when, where, how and for what purpose. Planning thus requires a clear consideration of alternatives and priorities.

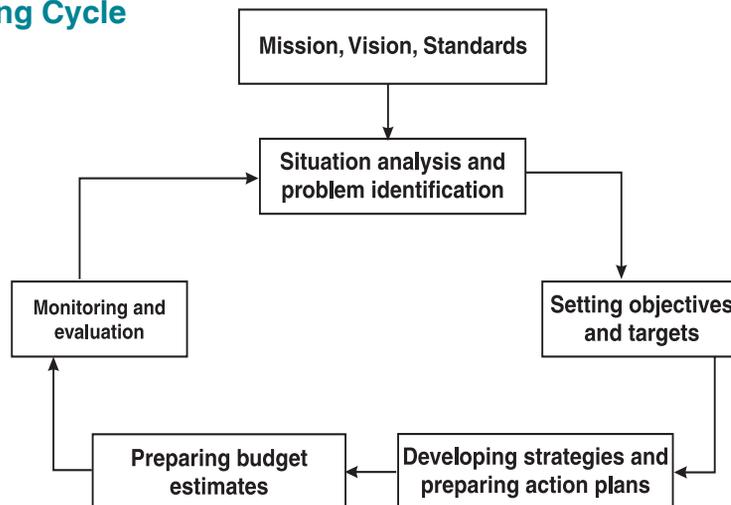
The development of a master plan starts with articulating clearly the strategic direction of the corporate entity, e.g. the government mission and vision with regards to the development of traditional medicine. The mission has to be fashioned from a philosophy (beliefs and values) that underlies the practice. The mission and vision work together. Goals and objectives need to be specified. These stages are critical in that they set the standard for what is to be achieved in the medium to long term.

After determining the required standards, an in-depth analysis of where to go and how to get there is necessary. Planning requires a step-by-step process for achieving certain objectives or goals. The process involves five primary steps:

- (a) Situation analysis and problem identification
- (b) Setting objectives and targets
- (c) Developing strategies
- (d) Preparation of action plans (including budget estimates)
- (e) Monitoring and evaluation.

The process of planning is not linear. Rather, it is continuous, each step providing information for the next step and feedback from the previous step. The last step provides insight and knowledge to begin again. For these reasons, the planning process is cyclical in nature, and dynamic and flexible in character (see diagram below).

### The Planning Cycle



## Situation Analysis

Planning relies on a good understanding of the existing situation. The information required for a thorough situation analysis may not be readily available. Information that can be used for an adequate situation analysis does not have to come exclusively from papers, reports, and studies, although official documents are generally a good place to start.

A technical situation analysis calls for an analysis of strengths, weaknesses, opportunities and threats (SWOT) It is carried out against the set standards as provided under the mission and vision. The questions to be asked are:

- (a) What are the strengths of the organization or sector that provide it with the advantage of being able to achieve the set standards?
- (b) What are weaknesses of the organization or sector that would impede performance with regards to the set standards?
- (c) What are the opportunities in the external environment of the organization or sector that can be seized to enhance performance in achieving the set standards?
- (d) What are the threats in the external environment of the organization or sector that may hinder performance in achieving set standards?

## Problem Identification

Information from the situation analysis should determine the key problems. Some problems are always more urgent or serious than others. An important part of planning is to decide which problems require the most immediate attention. This is the process of priority setting.

Priority setting can be very difficult and complex. It is likely to be a major source of argument and disagreement among working group members, especially during the first meeting. The team should try to keep in mind that different people have different perceptions of priority which have been moulded by their professional background, practical experience and personal interests.

There is no universally accepted formula for prioritizing problems in health service delivery. For this reason, decision-makers at the meeting should try to explain carefully the reasons for the priorities they have chosen. Answers to some of these questions can be relevant:

- (a) Is the problem of epidemiological concern?
- (b) Is there an acceptable technical solution to the problem?
- (c) Do civil society regard the problem with great concern?
- (d) Is the problem of great national and political concern?
- (e) Can the problem be solved at an affordable cost given district or national resources?

## Problem Analysis

The objective of analysing a problem is to determine the root causes of identified priority problems. Before objectives and targets can be established and before strategies can be developed to meet the objectives, the amenable causes of the priority problems should be analysed. Problem analysis involves a relatively simple analytical approach. Each member of the working team considers the question: “Why does this problem exist?” The group should discuss the root causes of each priority problem in order to arrive at a consensus opinion. Understanding the underlying causes of priority problems will help the group to easily establish objectives and develop strategies.

## Setting Programme Objectives and Targets

This step in the planning process seeks to answer the question “What is the destination or goal?” This step should clearly express intentions or objectives. An objective is a statement that specifies a particular outcome to achieve; it is a statement of intention. To guide implementation, it must be Specific, Measurable, Achievable, Realistic and Time bound, that is, SMART.

Targets are the milestones which indicate the progress being made in the achievement of objectives. They can be in the form of quarterly milestones that measure progress.

## Developing Strategies

A situation analysis and problem identification can provide a thorough understanding of the current situation. The next step is to develop strategies that will deal with the problems. A strategy is best understood as the overall approach or direction for a desired result.

Most problems are not usually caused by a single underlying factor but by many interdependent determinants. For this reason, planners will have to be able to develop more than one strategy to address a particular problem. For instance, if the lack of structured training has been identified as one of the priority problems in a country, then a strategy to address such a problem can be to develop a structured training programme for traditional medicine in that country. Such strategy may fall directly within the domain of the traditional medicine directorate. It is likely that one specific strategy may not be sufficient. Strategy development should include discussions about the potential to combine strategies or the possibility of implementing specific components of an overall strategy.

The final choice of strategies will depend on many variables. It is advisable to consider strategies for which resources are either routinely available or readily mobilized. Many strategies may be comprised of operational components or sub-strategies. If it is not immediately feasible to implement a complete strategy or combination of strategies, it may be possible to begin by introducing one or more strategy components.

## Preparing the Action Plan

The preparation of a detailed action plan entails a number of critical steps which should be followed in logical sequence. It is important to bear in mind that the plan of action should

encompass all the activities to be carried out within the medium to long term, including both routine and incremental activities. The critical steps in the preparation of an action plan are to:

1. Identify activities
2. Develop a time frame
3. Give people definite responsibilities
4. Identify resources for each activity
5. Define the expected outcome
6. Monitor and evaluate
7. Prepare a budget.

A number of activities or tasks are required for successful implementation of each strategy or strategy component. An initial step is to describe in considerable detail each of the activities which will need to be carried out in order to launch and maintain the strategy. This process greatly facilitates the next steps.

It is useful to specify when each activity should start. Some activities will continue indefinitely once they have been initiated, others will be completed after a specific period of time. Activities that have precise time frames should have a completion date. Only a few activities should take place within the same time period.

For each activity, it is important to identify who will be responsible for the actual performance. Additionally, the planning team must identify the individual or individuals who will be responsible for ensuring that each activity is carried out (i.e., supervision). It is advisable to avoid the temptation of assigning too many activities to only a few people or groups.

Planners must identify the resources required to implement each activity. Resources may be financial, material or human. Some activities may require resources that are not routinely available. In such cases, it is useful to note any assumptions made about additional resources. This stage of action plan preparation is critical; it is necessary to identify all the resources required for the set of activities so that they do not get stranded in the middle of implementation: quantity and unit cost, budget, sources of funding.

Planners should identify the expected outcome of each activity. This step will facilitate evaluation and monitoring. Monitoring is concerned with the observation of activities and programmes during the phases of implementation. It involves developing methodologies and tools for following the progress of activities. In addition, monitoring involves providing planners and managers with the information they need to correct unplanned deviations and get activities back on track. Monitoring tools include written and verbal reports, observation visits, meetings or review sessions, checklists.

Any plan requires a resource. The need for these resources and what they will be used for under the plan is the budget. A budget is the estimated financial requirements needed for planned activities. There are two main categories of budgets: recurrent and capital expenditure.

A recurrent budget includes resources required to take care of operational expenditures of the action plan. Capital expenditure takes care of the fixed assets such as buildings, equipment or vehicle.

Since resources are required for a master plan there is the need to prepare the budget to cover the whole period (e.g. 3-5 years). This should be broken down into annual budgets in order to make it easy to implement. Budget components include personal emoluments, travel and transport expenditure, utilities, maintenance, construction, furniture, equipment.

## 4.5 THE PROCESS OF PREPARING THE MASTER PLAN

The process of preparing the master plan should ensure that it is both technically sound and widely accepted by all key stakeholders. Hence, various steps are recommended in the development of the master plan.

### Initiating the process

There may be different starting points for initiating a master plan. A master or strategic plan may start as broad-ranging visions of how things should be; they may arise in response to specific changes within the health system, or its environment; or they may be required in order to resolve uncertainty or conflict among stakeholders. They also result from a participatory review of critical issues raised in policy formulation and review meetings, or they may be proposed by key individuals. A proposal for a master plan can also be initiated at the technical or political levels of the Ministry of Health.

Although the initiation process may be influenced by donor agencies, the process should ideally be initiated by the focal point for traditional medicine, i.e. a coordinating agency, management body or national authority. This will depend on the situation prevailing in individual countries. In Ghana, for example, the Traditional Medicine Directorate initiated the process, and preliminary discussions were held with the key persons of the Ministry of Health, e.g. the Director-General, Minister of Health and Director of Administration, who were consulted individually for support and commitment before the process began.

### Putting together a task team

The initial team members should be drawn from the key agencies working in the traditional medicine sector. The number should vary from 10 to 15 persons. The terms of reference of such a group will include, among others, preparing a proposal for the development of the master plan, serving as resource persons to facilitate the preparatory process and providing guidance during the implementation of the proposal. If appropriate, the team may be led by a consultant with requisite skills in the development of traditional medicine systems.

### Preparing the First Draft

The initial team will then prepare the initial draft. The team will first meet to define the scope of the work and share the task. They will then have a series of meetings to discuss what each person or group has prepared. One person (preferably a consultant) will put all the material together into a first draft. The group will then meet and finalize that document.

### Box 3: Suggested content of a master plan for traditional medicine

• Developing the Traditional Health Care System
• Strengthening Human Resource Development
• Providing Support for Research and Documentation of the Traditional Health System
• Establishing a System for the Promotion and Protection of Traditional Health Care Intellectual Rights
• Educational Programmes on the Conservation of Medicinal Plants
• Developing Herbaria, Botanical Gardens, Arboreta and Nurseries
• Financing Traditional Medicine
• Establishing a System for Certification of Traditional Medicine Products
• Instituting Quality Assurance Programmes
• Regulation, Monitoring and Evaluation Strategies
• Promoting Intersectoral Collaboration
• Management of the Strategic Plan

#### Meeting with Key Stakeholders

The master plan has to be marketed widely to solicit input from all stakeholders. The first draft master plan document should be disseminated to all stakeholders participating in traditional medicine in the country. After this, a meeting involving all the relevant stakeholders should be held to discuss the document. The meeting should be facilitated in such a way that there will be effective participation of all the stakeholders. The representatives of stakeholders participating in the meeting should work in technical groups. There should be an adequate number of persons in each group to address each of the priority problems identified. The meeting should be organized in such a way that discussions are open and frank. In addition, the facilitator should be flexible and make changes where and when necessary. This participation is a major way of increasing people's ownership and legitimization of the document.

The meeting of stakeholders should result in the completion of a second draft. It is the responsibility of the resource person(s) or consultant to complete this document.

#### Building Consensus on Second Draft

A number of consensus-building meetings should be held with key decision-makers within the health sector. Separate meetings should be held with:

- (a) Minister of Health
- (b) The Deputy Minister of Health
- (c) Directors within the Ministry of Health or departments of health services
- (d) Parliamentary group on health
- (e) Media
- (f) Cabinet.

This group of decision-makers can also participate in the stakeholders meeting. Their comments should be embodied in the document before a third draft is produced.

## Finalizing the Document

The third draft copy would then be submitted to an editorial team to edit the work. Often a lot of technical reports contain information that cannot be consumed by ordinary people. Since this document should be for the public domain, there is the need for an editorial team of experts with editing skills to refine all language or compositional issues, inconsistencies and misunderstandings. This team's work will finalize the document.

The Minister of Health or equivalent should sign the document before it is finally printed. After printing, copies of the document would be circulated to all stakeholders in traditional medicine. Key stakeholders who should have copies of the National Traditional Medicine Master Plan are:

- (a) Institutions conducting research in traditional medicines and medicinal plants
- (b) Drug regulatory authorities or bodies
- (c) Universities and teaching institutions involved in traditional medicine development
- (d) Federation of Traditional Health Practitioners Associations
- (e) Traditional Health Practitioners Councils
- (f) Associations of Traditional Health Practitioners
- (g) Standards Board
- (h) Medical Associations
- (i) Medical and Dental Councils
- (j) Nurses and Midwives Councils
- (k) Pharmacy councils.

### Box 4: Steps in preparing a master plan

Activity	Estimated Timeframe
Initiate the process	2 weeks
Constitute the core task team	1 week
Task team prepares first draft	4 weeks
Hold workshop to discuss first draft (meeting with stakeholders to produce second draft)	1 week
Build consensus on second draft	2 weeks
Finalize and disseminate the document	2 weeks
<b>Total</b>	<b>12 weeks</b>

## REFERENCES

1. WHO, Promoting the role of traditional medicine in national health systems: A strategy for the African Region, Harare, Zimbabwe, World Health Organization, Regional Office for Africa, 2000 (AFR/RC50/9).
2. WHO, Guidelines for the formulation, implementation, monitoring and evaluation of national drug policies, Harare, Zimbabwe, World Health Organization, Regional Office for Africa, 1999 (WHO/AFR/EDP/01.5).
3. Government of Sierra Leone, Ministry of Health and Sanitation, National Policy on Traditional Medicine, Freetown, Sierra Leone, 2004.
4. Federal Republic of Nigeria, Ministry of Science and Technology, Report of the Presidential Policy Advisory Committee, Lagos, Government Press, 1999.
5. WHO, Policy and legislative guidelines on intellectual property rights for indigenous knowledge and traditional medicine, Brazzaville, World Health Organization, Regional Office for Africa, *in press*.
6. Ekpere, J.A. The OAU Model Law: The Protection of the Rights of Local Communities, Farmers, and Breeders, and for the Regulation of Access to Biological Resources: An Explanatory Booklet, Lagos, OAU/STRC, 2000.
7. WHO, Alma-Ata 1978. Primary health care: Report of the international conference on primary health care, Alma-Ata, USSR, 6-12 September 1978, Geneva, World Health Organization, 1978 (Health for all series, No.1).
8. WHO, World Health Organization (2000) Health-for-all policy for the 21st century in the African Region: Agenda 2020, Harare, Zimbabwe, World Health Organization, Regional Office for Africa, 2000 (AFR/RC50/8 Rev.1).
9. WHO, Traditional medicine: Our culture, our future, African Health Monitor 4(1), 2003.
10. WHO, Guidelines on good agricultural and collection practices for medicinal plants, Geneva, World Health Organization, 2003.
11. WHO, Guidelines for registration of traditional medicines in the WHO African Region, Brazzaville, World Health Organization, Regional Office for Africa, *in press*.
12. WHO, Tools for continuing education of traditional health practitioners in primary health care, Brazzaville, World Health Organization, Regional Office for Africa, *in press*.
13. WHO, Training Tools for health science students and conventional health practitioners in traditional medicine, Brazzaville, World Health Organization, Regional Office for Africa, *in press*.

14. WHO, General guidelines for methodologies on research and evaluation of traditional medicine, Geneva, World Health Organization, 2001 (WHO/EDM/TRM/2001.1).
15. WHO, Clinical evaluation of traditional medicines used for the treatment of priority diseases, Brazzaville, World Health Organization, Regional Office for Africa, *in press*.
16. WHO, Traditional practitioners as primary health care workers, Geneva, World Health Organization, 1995 (WHO/SHS/DHS/TRM/95.5).
17. Government of Zimbabwe, Traditional Medical Practitioners Act, Cap. 27:14, Revised Edition, Harare, Government Printers, 1996.
18. Government of Ghana, Traditional Medicine Practice Act, Cap. 575, Accra, Ministry of Health, 2000.
19. Republic of Namibia, Traditional Healers Bill, Windhoek, Government Printers, 1999, as amended in 2000.
20. World Health Organization (1984). Preparation of specific legislation governing the practice of traditional medicine within the framework of national health legislation and ensure budget appropriation to allow the effective launching or development of a programme on traditional medicine: In: (Resolution, AFR/RC34/R8) on Report of the Standing Committee on Technical Cooperation among Development Countries (TCDC). WHO Regional Committee for Africa, Regional Office for Africa, Brazzaville.
21. Kasilo OMJ, Sofowora A, Soumbey-Alley E (2004). Situation analysis of traditional medicine in the WHO African Region: Proceedings of the international meeting on global atlas of traditional medicine, 17-19 June 2003, Kobe, Japan, World Health Organization, Centre for Health Development, 2003.
22. Government of Ethiopia, Code of Ethics for pharmacists practising in Ethiopia, Addis Ababa, Government Printers, 1996.
23. Federal Republic of Nigeria. National Traditional Medicine Development Programme. Catalogue of Formal government interventions in traditional medicine, Abuja, Nigeria, 1998.
24. Falkenberg T, Towards a global atlas of traditional, complementary and alternative medicine utilization: Provisional indicators for monitoring traditional, complementary and alternative medicine use, in Proceedings of WKC, International Consultative Meeting: Global information on traditional medicine/complementary and alternative medicine practices and utilization, Kobe Centre, Japan, 19-21 September 2001, Kobe, Japan, World Health Organization, Centre for Health Development, 2001.

## FURTHER READING

1. WHO, Development of national policy on traditional medicine: A report of the workshop on national policy on traditional medicine, 11-15 October 1999, Beijing, Manila, Philippines, World Health Organization, Western Pacific Region, 2000.
2. WHO, Apia action plan on traditional medicine in the Pacific Island countries, Manila, Philippines, World Health Organization, Western Pacific Region, 2001.
3. WHO, Final report on the African forum on the role of traditional medicine in health systems, Harare, 15-18 February 2000, Harare, Zimbabwe, World Health Organization, Regional Office for Africa, 2001 (AFR/TRM/01.1).

# Annex : 1

## Indicators For Monitoring And Evaluating Traditional Medicine Development [24]

### Background (BG) Indicators

- BG1 Total population
- BG2 Average annual growth of the population
- BG3 Life expectancy
- BG4 GDP per capita
- BG5 Infant mortality rate
- BG6 Maternal mortality rate
- BG7 Top ten causes of morbidity
- BG8 Top ten causes of mortality
- BG9 Total number of prescribers (including prescribing doctors, nurses, etc.)
- BG10 Total number of traditional, complementary and alternative medicine (TM / CAM) providers within and outside the conventional health system
- BG11 Total health expenditure for the conventional health care sector (total, primary, secondary, tertiary)

### Process (PR) Indicators

- PR1 Estimated prevalence of national TM/CAM use. (A)
  - PR2 Estimated prevalence of the five most popular individual therapies used. (A)
  - PR3 Estimated prevalence of national traditional medicine use. (A)
  - PR4 Medical determinants for TM/CAM use. (B)
  - PR5 Patient satisfaction and perceived outcome of TM/CAM treatment. (B)
  - PR6 Sociodemographic characteristics of consumers associated with the use of TM/ CAM. (B)
  - PR7 Total out-of-pocket payments and total national expenditure estimates for TM/ CAM utilization. (C)
- (A) Indicates that this is a priority and is likely to be feasible to apply.
- (B) Indicates that this is important but could be less feasible to apply.
- (C) Indicates that this is of slightly less importance and may present problems of feasibility.

## Structural (ST) Indicators

- ST1 Is there an official traditional (TM), complementary and alternative medicine (CAM) policy?
- ST2 Is there TM/CAM legislation of a general nature?
- ST3 Are certain forms of TM/CAM regulated for practitioners?
- ST4 Are certain forms of TM/CAM regulated for medications?
- ST5 Are all or only certain TM/CAM providers legally recognized?
- ST6 Are there professional categories entitled to provide TM/CAM?
- ST7 Do education and training for TM/CAM providers exist within the conventional health system?
- ST8 Do education and training for TM/CAM providers exist outside the conventional health system?
- ST9 Is there a ministry, institution or national expert committee which has a mandate for includes TM/CAM control, information or research?
- ST10 Is there a national voluntary self-regulatory body for TM/CAM?
- ST11 Are there any financing systems that contribute to the provision of certain TM/CAM therapies in the public sector?
- ST12 Was there a TM/CAM user survey conducted in the past twenty years?