POLICY GUIDELINES

ON

TRADITIONAL MEDICINE DEVELOPMENT

Ministry of Health **2005**

TRADITIONAL MEDICINE POLICY

Preface and Introduction

In Ghana successive governments have recognized the importance of traditional medicine. The formation of the Ghana Psychic and Traditional Healers Association in 1961 and the establishment of the Centre for Scientific Research into Plant Medicine in 1975 attest to this fact. Also in 1991 the government established a unit for the coordination of Traditional Medicine (which is now Traditional and Alternative Medicine Directorate) which was followed by the setting up of the Food and Drugs Board in 1992, which among others, is to certify the sale of Traditional Medicine products to the public. In 2000, the government enacted the TMPC Act, Act 575 for the establishment of Traditional Medicine Council which is tasked with the responsibility for the registration of all Traditional Medical Practitioners in the country. An Alternative Medicine Bill is yet to be passed in parliament.

Although all these documents provide a legal policy framework for the development of Traditional Medicine, there is no single document that coordinates the general policy direction of government in the area of traditional medicine.

This policy document has been designed to fill this gap. The object is to provide a general policy direction or framework within which government's short to long term plans on TM would be based. It cuts across sectoral boundaries and provides a national position for which all sectors have to buy into.

Almost all the relevant traditional medicine institutions and organizations were involved in the process of developing the document. Representatives were drawn from the Ministry of Health, Ghana Health Service, Food and Drugs Board, Ghana National Drugs Programme, Centre for Scientific Research Into Plant Medicine, Centre for Scientific and Industrial Research, Ghana Federation of Traditional Medicine Practitioners Associations (GHAFTRAM), Ghana Medical Association, Nurses and Midwives Council, Pharmacy Council, World Health Organization and DANIDA. Others included were Sociology and Biochemistry Departments of the University of Ghana and the Faculty of Pharmacy of the Kwame Nkrumah University of Science and Technology.

It is hoped that the document will be relevant to all government institutions working towards the development of Traditional Medicine.

Signature

EXECUTIVE SUMMARY

It is the policy of government to continue to research and develop Traditional Medicine with the aim integrating the products and returns into the health care delivery system of the country. The potential of traditional medicine has been recognized by successive governments. The establishment of the Traditional and Alternative Medicine Directorate of the Ministry of Health is to coordinate the activities of policy initiation and implementation.

For the Directorate to work effectively there is the need for a general policy direction for coordinating activities in the area of traditional medicine. This is what this document seeks to address.

The objective is to provide a general policy direction or framework within which government short to long term plans on Traditional Medicine would be based. The policy cuts across sectoral boundaries and provides a national position for which all sectors have to use as a basis for developing plans for traditional medicine development.

The policy focuses on the following areas:

1. Practice of traditional medicine and regulatory legislation.
2. Re-organization and management of traditional medicine associations.
3. Intellectual Property Rights Protection
4. Professionalization of TM/CAM through formal training
5. Research and Product Development
6. Public I.E & C on Rational use of Traditional Medicine.
7. Standardization, quality assurance and large scale production.
8. Documentation, information exchange and baseline data collection.
9. Biodiversity conservation and sustainable harvesting.
10. Global Networking and Collaboration
11. Technology transfer and commercialization of best products and practices.
12. Integration of TM/CAM into national health systems and commercialization.

POLICY GUIDELINES AND ACTIONS

1.0 Practice of Traditional Medicine and Regulatory Legislation

1.1 Situation:

There is high patronage of the Traditional Medicine (TM) for many reasons including belief, trust, proximity and cost and mode of payment. Thus TM is a national asset. It provides employment to indigenous people and there is the need to improve the practice.

The main problems affecting the practice of Traditional Medicine include the lack of information on practitioners including their qualification, registration, educational background, location, number and the products used in their practices. Other problems include inappropriate premises for practice, inadequate record keeping by practitioners, inadequate facilities for diagnosis and the use of un-standardized products.

Furthermore, there are varied and unknown TM practices in the country. Some of these practices particularly TM, are confined to families and the practice is home-based. These practices are not organized for training purposes. There are, also too many hawkers and peddlers practicing in the system.

Alternative Medicines in particular are mainly foreign and imported. In most cases there are no recognized locally accredited training institutions and/or professional bodies.

1.2 Policy:

i) All TMPs shall be required to register an association and the TM Council with the view to enhancing the practice and eliminating quacks in the system.
ii) To assist the genuine practitioners, the umbrella association of TM shall be encouraged to organize training and educational programmes on good manufacturing practices.
iii) TMPs shall keep accurate records of all their practices
iv) TM practitioners shall be encouraged to use modern facilities to diagnose and monitor management of patients.
v) TM shall be provided in all public health institutions. The purpose is to offer patients/clients options of health service from which to choose.
vi) Appropriate standards of practice shall be set as and when facilities improve to make it easier for enforcement of legislation.

1.3 Implication:

To ensure that TMPs keep accurate record on their practice require the design of appropriate record keeping formats that can easily be filled by practitioner given their education background. Also, TAMD in collaboration with the Traditional Medicine Practice Council may need to develop acceptable standards of practice for Traditional

Medicine Practitioners. Guideline for providing TM service in public health institutions shall be developed and implemented.

2.0 Organization and Management of Traditional Medicine Associations.

2.1 Situation:

The obstacles impending the setting up of a single accountable organization representing TM practitioners include the presence of many splinter groups each with divergent views, visions and expectations. Individual association appears not to be well represented at the grassroots level and there is often misunderstanding and lack of information sharing amongst stakeholders. Suspicion between members of different groups, personality projections, and power and ego clashes are not uncommon.

2.2 Policy

The TAM Directorate shall be strengthened to mobilize and organize practitioners at all levels. This is to ensure that all the groups are well organized with the view to increasing the flow of information available to all TM practitioners. The management of the organization of practitioners shall be decentralized to the regional, district, sub-district and community levels. Traditional Medicine Practice Council will be required to regulate practices particularly in the private sector.

2.3 Implications

Establish administrative structure at regional and district level to develop level specific plans to monitor and evaluate Traditional Medicine Practice in collaboration with the Associations. Also, personnel at these levels would have to provide management support for the organization of the associations.

The structure for managing and regulating practitioners would have to be formalized through a national legislation that will lead to formation of a regulatory Council. The Executives of GHAFTRAM at regional and district levels will need to be equipped with managerial skills and orientation to enable them function effectively in keeping the groups together. Regular meetings shall be held between TAMD, and the Traditional Medicine Practice Council to review organizational problems and resolve them.

3.0 Intellectual Property Rights Protection

3.1 Situation:

Currently, there is an apparent lack of well-defined legislation covering patenting with respect to traditional medicine products and procedures. Among practitioners there is ignorance about the meaning, implication and workings of patent laws and rights as well

as the availability of trademark registers and protection. Generally, there is a lack of knowledge among TMPs on the need for intellectual property rights protection.

Traditional Medicine Practitioners do not share information on their knowledge (practice and preparation) due to:

(i) Lack of trust
(ii) Fear of loosing their livelihood
(iii) Oath of secrecy
(iv) Maintenance of their status and reputation

The above observations are reasons given by TMPs for their unwillingness to disclose vital information and knowledge of their practices and products. It is worth nothing that plants cannot be patented but knowledge of use of plants and formulation of the plant products can be patented.

3.2 Policies:

(i) TM practitioners shall be educated on all aspects of patent, copyright and trademark laws

(ii) IPR system in respect of indigenous knowledge of TM practitioners and other scientists shall be protected and harnessed.

3.3 Implication

There is the need to develop a generic system for TMP knowledge as well as guidelines for IPR. Also, the Ministry may need to set up a system to facilitate the processes involved in gaining access to IPR for TMPs. Moreover, TMPs would have to be trained no how to keep records or document their findings that make scientific sense.

4.0 Professionalization of Traditional Medicine through Formal Training

4.1 Situation:

There is lack of adequate training for practitioners. There are no established institutions for training TMPs and their trainers. There is no TM component in the syllabi for the training of orthodox medical practitioners and lack of motivation for orthodox practitioners who embark upon TMP training programs.

4.2 Policy:

(i) Training shall be provided for TM to improve their knowledge and skills of practice. The cost of such training shall be borne by the government.
(ii) Training curriculum shall be developed for TMP training at all levels.
(iii) Allopathic health practitioners shall be encouraged to study and practice TM and vice versa.

4.3 Implication

Already training needs assessment has been conducted. A training manual has also been prepared. The next step is to design training programme and schedule that would fit the convenience of the practitioners given that they have other economic interests.

TAMD in collaboration with the Traditional Medicine Practice Council has to put in Place a system for following up trained practitioners to assess their performance after training so that in-service-training programmes can be instituted for them.

5.0 Research and Product Development

5.1 Situation:

Research into TM is hampered by the lack of funds, personnel and facilities. Researches that are carried out is uncoordinated nationwide with little or no prioritization. There is very little interaction between scientists and practitioners and generally, there is a worrying lack of recognition of the need for the benefits of research and development towards improving practice.

5.2 Policy:

(i) TM practitioners shall be trained in research methods to enable them carry out research and documentation of results of their practices.
(ii) Guidelines shall be provided for efficacy and safety studies in relation to TM medicine products to ensure relevance.
(iii) Guidelines shall be provided for clinical trials of Traditional Medicine products.
(iv) TM practitioners shall be required to document and report all adverse effects of plant medicine products and all reported cases shall be investigated.
(v) Interaction between TM practitioners and Allopathic practitioners shall be encouraged through research. Seminars, workshops and symposia.

(vi) All national research institutions shall be equipped to undertake research into TM practices to advance the development of TM

(vii) The TAMD shall seek entrepreneurial linkage for product development for commercial manufacture of TM product with proven effectiveness and in the areas of public concern.

5.3 Implications

The implications are the need to develop a research agenda in relation to traditional medicine and specific diseases of public health concern. Also appropriate and harmonized research methods need to be developed for TMPs.

The capacity to promptly investigate adverse reactions needs to be developed. This requires additional human resource with the requisite skills at the proposed collection centre.

6.0 I. E and C on Rational Use of Traditional Medicine

6.1 Situation:

There is inadequate knowledge among a section of the general public of the capabilities and benefits of TM. Thus, a section of the public has some misgivings about plant medicine products.

The health care system is bias towards allopathic medicine. These problems are not helped by the fact that very little documentation exists on the practice and products of TM.

6.2 Policy:

(i) Public education shall be intensified on the values, benefits and dangers associated with both practices.

(ii) The Directorate shall collaborate with Ministry of Education/Ghana Education Service to incorporate into the school university curricula studies on Traditional Medicine.

(iii) The media shall be trained and supported to promote TM.

6.3 Implications

An information, Education and communication strategy and programme should be drawn and implemented. Guidelines for advertising TM product should be developed taking into consideration national guidelines on advertising drugs.

There should be training and orientation programmes for media houses and personnel on advertising of TM products.

7.0 Standardization, Quality Assurance and Large-scale Production

7.1 Situation:

Traditional medicines are being dispensed to patients. Some products are being sold to the public without established evidence of safety and efficacy. Production of traditional/plant medicine product do not meet the standards of Good manufacturing practices (GMP) and they lack standardization. Some practitioners are not willing to comply with Food Drug Board's (FDB) requirements to disclose the identity of the plants they use for their product preparation.

7.2 Policy:

(iii) TM practitioners shall be assisted to standardize their medicinal product to ensure uniformity in the batches that are offered for sale.
(iv) Manufacturing premises shall be regularly inspected to ensure good manufacturing practices (GMP).
(v) TM practitioners shall be required to disclose vital information on their products before registration of traditional medicinal products
(vi) MOH shall promote the use of TM products by allopathic practitioners.

7.3 Implication

The training of TM practitioners should include standardization of medicinal products and good manufacturing practices and a system for monitoring and evaluating the competency of TMPs should be put in place.

7.4 Situation: Evaluating Efficacy and Safety

(a) Availability of Testing Facilities

The centres that have some facilities for testing TM products are:

- The centre for clinical pharmacology and therapeutics, University of Ghana Medicinal School
- The Noguchi Memorial Institute for Medical Research, Legon
- The Faculty of Pharmacy, Kwame Nkrumah University of Science and Technology
- The Biochemistry Department, University of Ghana Legon
- The chemistry Department, University of Cape Coast
- Centre for Scientific Research into Plant Medicine.

However, these institutions are not fully equipped to carry out or conduct all tests required. There is minimal testing for safety and inadequate quality assessment. The institutions that can perform chemical analysis are also inadequate. The Institutions that can perform microbiological analysis are:

- ❖ Ghana Standard Board
- ❖ Noguchi Memorial institute for Medical Research

Those that perform biological testing (safety and efficacy) are

- ❖ Noguchi Memorial institute for Medical Research
- ❖ Some Faculties and Departments of the University of Ghana and the University of Science and Technology.
- ❖ Centre for Scientific Research into Plant Medicine.

(b) Geographical access to testing facilities

All of these institutions, apart from the Faculty of Pharmacy are situated in the southern sector of the country limiting access to practitioners in the North.

Financial access to testing facilities

The main problems in this area include:

- The relatively high cost of testing
- The poor financial status of practitioners generally and

The lack of adequate human and equipment resources with respect to the testing centres.

7.5 Safety and Efficacy

Situation:

The Centre for Scientific Research into Plant Medicine was established in 1975 to research into plant medicine, standardize their preparation and ensure safety of herbal medicine products.

Policy:

(i) TM practitioners shall be encouraged to disclose information on their products that would be vital for complete evaluation (safety, efficacy and quality) of their products. This activity is performed for and on behalf of the Food and Drugs Board which gives authorization for manufacture and sale of herbal medicines. Over 1000 herbal medicines have been screened for safety since 2001. Many herbal remedies in circulation and in use at the clinic level have however not been tested. Some practitioners do not feel the need for such tests, whilst other site lack of finances to pay the fee for such tests to be done on their products.

(ii) The regulatory bodies shall set the minimum standards for safety and efficacy. These procedures and standards shall be harmonized for use by all research units and universities.

(iii) For the short term, institutional strengths in conducting specific and specialized tests shall be identified and used as a guide to direct requests to the appropriate institution.

(iv) The Ministry of Health or the Traditional Medicine Practice Council shall establish regional/district collection centres where materials for testing are submitted for onward transmission to appropriate testing centres.

(v) A testing centre shall be established in the North.

(vi) Financial support would be provided to improve the safety, quality and efficacy of TM products in use in Ghana. Special consideration shall be given in products for diseases of public health concern. Existing and future testing centres shall be supported in terms of equipment, human and infrastructural development.

7.6 Implication:

Ministry of Health is to put in place mechanisms to assure TMPs of their Intellectual Property Rights. There is the need for legal review on Intellectual Property Right in respect of TM.

Establishment of collection and testing centres require the acquisition of office accommodation in the respective regions and staff employed. A scheme of service for staff may have to be developed as well and training provided to equip them to the tasks.

In the case of testing centres a range of equipment needs to be determined and acquired.

8.0 Documentation, information exchange and collection of baseline data

8.1 Situation:

A number of raw materials, plants, animals and minerals are used by TMPs in preparing their medicines. However, not all of them have been documented.

8.2 Policy:

(i) TM practitioners shall be encouraged and supported to document all the biological/medicinal products they use in their practices.

(ii) Government shall provide financial support for recognized institutions to document TM raw materials products in the country.

(iii) To be able to set mediators and targets, there is need to collect adequate baseline data

8.3 Implications:

A national library for TM shall be set-up to keep all relevant research works and information which could serve as learning centers for TM students and trainees.

9.0. Biodiversity Conservation and Sustainable Harvesting.

9.1 Situation:

Generally, traditional medicinal products especially plants are collected from the wild. However, this is not done efficiently in that plant parts are removed without replacement. This is complicated by large-scale collection for export that threatens extinct of some species.

Added to these is the fact that there is lack of expertise in cultivation and collection of herbal products. Other problems threatening maintenance of sustainable biodiversity include:

- A lack of environmental awareness within the general population leading to destruction of the environment as a result of farming practices, mining, industrialization and urbanization;
- Lack of data on national biodiversity
- Poor planning and / or enforcement of planning regulations.
- Misidentification

9.2 Policy:

(i) The commercial collectors shall be educated and trained on techniques of sustainable harvesting.

(ii) Large-scale collectors shall be registered and their activities monitored.

(iii) All large-scale Commercial collectors of medicinal plants shall be required to provide their programme on replanting to enhance monitoring and sustainability.

(iv) Commercial collectors of medicinal plant parts shall be made to use some of their resources to replenish the plants they destroy.

(v) Current biodiversity in the country shall be assessed and usage documented.

(vi) TM practitioners shall be encouraged and financially supported to cultivate their sources of materials.

9.3 Implication:

Biodiversity Planning needs to be undertaken to ensure effective utilization and sustainability. Also guidelines for collection of biodiversity will need to be prepared and used as part of training materials of TMP.

10. 0 Global Networking and Collaboration

10.1 Situation:

World Health Organization (WHO) has made resolution and established conventions on problems associated with development of Traditional Medicine globally. It is established that Traditional medicine has played a successful intervention in the global health care delivery system and best results are scattered all over the world. There is therefore the need for networking, collaboration and exchange of information, locally and internationally to be done among stakeholders.

10.2 Policy:

A directory of international collaborator should be prepared and reviewed continually.

Provision should be made for key staff to attend relevant local and international courses, workshops and conferences.

10.3 Implications:

Funds should be sourced to finance organization and attendance of convergence meetings and workshops for the purpose of developing policies, tools and sharing of information.

11.0 Technology Transfer and Commercialization

11.1 Situation:

The main strength in this area is the availability of ready markets for the products of TM. However several problems militate against commercialization, of TM products and these include the absence of supporting industries for commercialization, poor funding, poor packaging and labelling and absence of standardization. There is also an absence of a resource base e.g. materials, equipment, personnel.

11.2 Policy:

(i) Large scale commercialization of TAM products shall be encouraged and financially supported.

(ii) Extensive local use of TAM medicinal products shall be encouraged through education and provision of such products at public health institutions.

11.3 Implication:

Implication is to work with other agencies, e.g. Ministry of Lands and Forestry and Export Promotion Council to ensure proper planning and urination of the available Biodiversity in the country.

Use of modern knowledge by TMPs may need to be developed to enhance the development of traditional medicine practice in the country.

12.0 Integration of TM/CAM into national health systems and commercialization.

12.1 Situation:

Currently Traditional Medicine Practitioners (TMPs) and Orthodox Medicine Practitioners (OMPs) are working/operating separately and there is mistrust between OM and TM Practitioners due to ignorance as they lack information and education on the roles of each practice. Thus, there is a very loose co-operation between OMPs and TMPs.

While in some cases TMPs are rendering some useful services, in many cases their practices are not up to expectations. TMPs will education and training to upgrade their knowledge and skills. There is the feeling among TMPs that they are not being accorded the needed recognition by OMPs. Thus, there is resistance to integration with the allopathic health care system.

There is also lack of coordination between national institutions like the Food and Drugs Board. Ghana Standards Board, and Universities etc.

12.2 Policy:

(i) The Traditional Medicine Practice Council (TMPC) shall encourage training and education of TMPs to upgrade their knowledge and skills with the view to strengthening the co-operation between TMPs and OMPs

(ii) For the short term, the TMPC shall organize training programmes along the lines organized for TBAs to improve upon the practices of TMPs.

(iii) Government shall support higher institutions which would like to mount training programmes in TM.

(iv) The Ministry shall encourage collaboration between TM and OM practitioners through education on all sides to arrive at cooperation.

(v) Integration shall take place at the product level by putting them at the disposal of both practitioners.

13. 2 Implications:

This situation shall be reversed by organizing regular inter-sectoral meetings of stakeholders to discuss specific areas of common interest. TAMD would be at the centre of such meetings.

Concluding Remarks

Many of the policy proposals made already exist or have been made in the Traditional Medicine Final Draft Report, April, 1994. This is so with many other polices, laws and regulations. There seem to be some kind of inertia when it comes to implementing policies when there is lack of national direction and coordination. Thus, the Directorate of Traditional and Alternative Medicines shall lead in strengthening coordination of Traditional Medicine Practice in the Country.

The Policy Formulation group resolved that it would act as advocacy and support group in ensuring the implementation of the Policy on Traditional Medicine.