KEYNOTE ADDRESS

POLICIES AND DIRECTIONS FOR TRADITIONAL MEDICINE AND MEDICINAL PLANTS: THE WAY FORWARD IN THE NEXT DECADE.

~~TO BE DELIVERED~~ BY

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ABSTRACT

The role of traditional medicine in health care delivery in the developing countries is well known and acknowledged. The substantial contribution of natural-based products to orthodox medicines cannot be overlooked. The current global resurgence in the desire and willingness to use natural products has posed new challenges regarding the development of botanicals. Thus, there is an urgent need to design scientific/clinical interventions which can be used in the research and development of standardized phytomedicines which are safe, effective, affordable, acceptable and of consistent quality. Extensive networking of researchers and institutions will facilitate information gathering and sharing as well as collaboration leading to accelerated development of standardised phytomedicines. In order to protect the innocent general public from potential toxic effects of some plants and adulteration of phytomedicines, government regulation of the products and practice of traditional medicine is absolutely necessary .Appropriate policies, regulatory structures and allocation of reasonable resources as well as their judicious use are absolutely essential vis-a- vis research and development of standardized African phytomedicines. Specific priority diseases should be identified and targeted. Available ethnomedical evidence and literature data should be accumulated. Initial clinical observational studies may indicate the potential clinical efficacy and safety of a particular phytomedicine. Bioguided fractionation may lead to the potential bioactive fraction or fractions which can be used for subsequent studies while the whole crude total extract serves as the control. Standardization processes involving the raw materials, processed materials, formulated products and all the processes involved should be established in accordance with Good Laboratory Practice principles. The product should be assessed toxicologically. Intellectual property rights as well as mechanisms for equitable benefit sharing should be properly addressed. Plant raw materials supplied for post-harvesting processing in the quantities required and at all times they are needed may constitute the most crucial element vis-a-vis local production of a standardized phytomedicine. Samples required for clinical trials should be produced at pilot scale using Good Manufacturing Practice principles. Controlled clinical trials (phases II and III) should be conducted in accordance with Good Clinical Practice guidelines using appropriate reference orthodox medicines for the control groups. Registration with

appropriate regulatory authority as an essential phytomedicine, local production , marketing and post-marketing surveillance may lead to the rationale use of the phytomedicine within and beyond Africa.

1) HEALTH SITUATION IN AFRICA.

Plants, animals, water and minerals constitute the major resources used by man for promotive, preventive, curative and rehabilitative health since the creation of man. The Traditional Health Practitioners (THPs) acquired their knowledge and skills through observation, spiritual revelation, experience, training, and direct information from their predecessors. Generally, African Traditional Medicine (ATM) is based on holistic approach vis-a-vis management of the patient involving the body, soul and spirit.

The advent of the colonialists to Africa brought orthodox medicines to Africa over 100 years ago. Undoubtedly, modern science and technology has revolutionized human health. In spite of the development of resistant strains of micro-organisms, mortality associated with common infectious diseases has declined significantly with attendant increase in life expectancy. The eradication of small pox globally is another evidence of the efficacy of orthodox medicine. Incidentally, the impact of orthodox medicine has not dramatically changed the health status of most Africans. Life expectancy was 53 years in 1995 while in Latin America and the developed world the corresponding figures were 69 and 74 years. Furthermore, infant mortality rate was 89 per 1000 life births in Africa while in Japan and Germany the rates were 4 and 5 per 1000 life births in 1998. According to WHO, about 80% of people inhabiting the Third world countries rely essentially on traditional medicine for their primary health care needs. Infact, in most cases, traditional medicine is all the health care service available, accessible and affordable to them. Over 33% of the world's population have no regular access to the most basic essential medicines .Infact, in the poorest countries in Africa and Asia , over 50% of the population lack access to essential medicines. In this situation, the significant contribution of traditional medicine as a major provider of health care services in Africa is always acknowledged. For example, in Ghana and Zambia the ratio of Orthodox Medical Practitioners (OMPs) to the population is one to 2000 while the corresponding figure of THPs to the total population is 1 to 200. Unlike Asia and Europe, African Traditional Medicine has not witnessed any significant development regarding policy directions, regulatory institutions,

resource allocations, integrated focused research and development activities, controlled clinical trials, local manufacturing of standardized traditional medicines and registration of traditional medicines for use in public health sector.

Infectious diseases constitute about 45% of all mortalities in Africa and S.E. Asia. According to WHO, every three seconds a young child dies , in most cases, from a preventable infectious diseases. Furthermore, about 3,000 people die daily from malaria while another 1.5 million die from tuberculosis every year. WHO-AFRO has indicated that HIV/AIDS, malaria, sickle cell anaemia, diabetes and hypertension are the priority diseases in Africa.

The current pandemic of HIV/AIDS has further complicated the health problems in Africa consequently reversing some of the socio-economic gains of the last 25 years in Africa. The latest UNAIDS figures indicate that about 28 million Africans are infected with HIV while 80% of all new infections occur in sub-Saharan Africa – home to only 10% of the world. It ahs been estimated that about 30,000 Africans have access to antiretroviral agents. It is not surprising that Africa has lost over 15 million people since the beginning of the epidemic about 20 years ago. Definitely, urgent interventions are needed to halt these disastrous trends. Can the immense biodiversity in Africa provide safe, effective and affordable medicines for HIV/AIDS?

Malaria is the commonest cause of outpatients hospital attendance in all age groups and the commonest cause of hospital admission in children in Africa (Salako, 1999). About 10% of all childhood deaths are due directly to malaria and possibly 25% are indirectly due to the complications of malaria. Unfortunately, *Plasmodium falciparum* which accounts for about 80% of malaria infections in Africa has developed resistance (up to 40% in some areas) against the most common and affordable anti-malarial agents (Sowunmi et al, 1995). What are the prospects from on-going research in this field in Africa?

It is noteworthy that researchers at the Centre for Research into Plant Medicines (CRPM) in Mampong-Akwapim, Ghana have identified some bio-active moieties in an indigenous plan-*Cryptolepis sanguinolenta.* Research efforts at the Institute of Traditional Medicine (ITM) , Bamako, Mali , Kenya Medical Research Institute (KEMRI), Nairobi, CRPM, Ghana

and National Institute for Pharmaceutical Research and Development (NIPRD), Abuja, Nigeria have gone beyond animal studies. Since ITM introduced their anti-malarial herbal medicine into the Malian market over five years ago, the demand has been more than the supplies-an evidence of its clinical efficacy. The products developed at KEMRI, CRPM and NIPRD are currently being subjected to preliminary pilot clinical trials with the financial support of WHO, Geneva.

The African Pharmacopoeia compiled and published by the OAU/STRC in 1985 included *Fagara* species for use in the management of sickle cell anaemia. The original work was done by Sofowora and his colleagues at the University of Ife. Recently, Wambebe et al (2001) published their clinical data regarding the use of a standardized herbal medicine (NIPRISAN) formulated from indigenous medicinal plants for the prophylactic management of sickle cell anaemia. These research and development activities in Africa suggest that there are potentials for the development of new medicines for use against the priority diseases in Africa.

2) CURRENT POLICY DIRECTIONS

2.1 WHO DRAFT POLICIES

It has been justifiably emphasized that political commitment regarding recognition of traditional medicine and formulation of policies, legal framework for the practice of traditional medicine and appropriate regulations are the most critical elements for the advancement of traditional medicine. WHO (AFR/RC50/9, 2001) included policy formulation as one of the priority interventions vis-à-vis promotion of traditional medicine in health systems. WHO-AFRO has developed some model documents including National Policy on Traditional Medicine, Code of Ethics of Traditional Health Practitioners and Traditional Health Practitioners Bill, among others. The institutionalization of traditional medicine in Africa cannot be achieved without adoption of these WHO draft documents. The pioneer status of China in traditional medicine has been linked directly to the inclusion of traditional medicine in the Chinese constitution in 1954. Although there has been similar efforts by WHO-AFRO regarding draft policy documents, none has been as comprehensive as the current draft documents. Regional Member Countries (RMC) are urged to adapt these draft documentations as a priority intervention in promoting traditional

medicine in their countries. According to the survey sponsored by WHO , most RMCs have not developed national policies on traditional medicine, enact legislation, establish regulatory and institutional structures as well as develop codes of ethics and conduct for the practice of traditional medicine (AFR/RC50/9, 2001). Thus, these draft documents will be most useful to RMCs in this new policy direction.

2.2 BIODIVERSITY ISSUES

Bio-prospecting of African biological resources by big pharmaceutical companies and research institutions has recently witnessed an upsurge in accordance with similar searches in the Tropical forests of the world. Unlike the synthetic route for developing new medicinal agents where the success rate may be 0.001% , the success rate with the search for new therapeutic moieties based on medicinal plants used in TM can be as high as 74%. Unfortunately, many African researchers, THPs, plant gatherers, traders, etc knowingly and unknowingly have become active suppliers of the plant raw materials to Western investigators at very low one time cash payments. The general poverty which prevails most African communities has facilitated this kind of unfair transaction. The paradox is that the medicinal plants acquired in Africa depletes the continent of its biodiversity and makes the people eventually poorer while strenghthening the economies of the developed nations by selling the finished products at high rates to Africa .

In this unacceptable situation, it is remarkable to note that African governments have made concerted efforts to resist such practices. For example, at the Third Ministerial Meeting of the World Trade Organization in Seattle in November 1999, the African Group of Ambassadors , OAU and African Economic Community warned that :

"*There is no transparency in the proceedings and African countries are being marginalised and generally excluded on issues of vital importance for our peoples and their future----------We reject the approach that is being employed and we must point out that under the present circumstances, we will not be able to join the consensus required to meet the objectives of the Ministerial Conference . We therefore expect that our concerns as consistently expressed by African countries be adequately addressed.*"

This position taken by the African Group was partly responsible for the collapse of the Ministerial Meeting.

In most cases, RMCs lack experts in various aspects of biodiversity. Thus, training programmes on various provisions of the Convention on Biodiversity can be organized by United Nations Environmental Program (UNEP) and other UN agencies. It has been estimated that about 90% of the economic life of Africa is based essentially on natural resources while approximately 90% of the biodiversity of Africa lies outside government protected areas (CBD Convention,200). Thus , the sustainable use of natural resources is a pre-requisite for the continuation of life in all its diversity of genes, species and ecosystems. Any intervention through development, conservation, cultivation, local production and public utilization should be adequately planned and carefully examined. Such planning activities require proper empowerment of the indigenes with the requisite knowledge in various elements of biodiversity. Examples include legal and social aspects of access to plant species, benefit sharing and approaches to negotiations with multinationals and investors. Short, medium and long term considerations on the benefits, land acquisition and ecosystem should be included in the training programmes. The indigenes should be trained in possible local initiatives which can add value to the products .Drafting of various research and contract agreements should also constitute important components of the training.

2.2.1 AFRICA's PROPOSED REVISION OF TRIPS AGREEMENT.

The African Group insisted on the revision of TRIPS Agreement and consequently affirmed :

- Their rejection of the patenting of life forms
- The need for the TRIPS Agreement to exclude microorganisms and microbial processes from patentability.
- The importance of maintaining flexibility within Article 27.3 of TRIPS for *sui generis* systems to protect plant varieties and the need for such systems to protect the innovations and practices of farming communities.
- The need for TRIPS to be harmonized with the CBD and the International Undertaking and
- The importance of relaxing the exclusive rights of patent holders in respect of drugs listed as essential by the WHO.

2.2.2 AFRICA'S POSITION ON BIODIVERSITY.

The initiatives by OAU have increased the awareness of Member countries to the urgency of biodiversity issues and consequently legislating laws and regulations to implement them in a fair and equitable manner. In countries that have significant plant breeding activities , such as South Africa, Zimbabwe and Kenya , national legislations existed regarding IPR over plant varieties in accordance with TRIPS Agreement. In Zimbabwe , such legislation is currently being reviewed so as to generate a *sui generis* legislation in conformity with the model developed by SADC . Other countries like Zambia , are committed to a Plant Breeder's Act presently being formulated through wide consultation . In Uganda, a draft legislation to protect community rights is also being developed with the involvement of all the stakeholders. Similarly, such policy initiatives on the appropriate and acceptable laws and regulations for protecting Traditional Knowledge and Framers Rights are in progress in other countries like South Africa, Ethiopia, Nigeria, etc.

These efforts by various African countries are quite commendable and their full implementation should be pursued with total commitment by the governments of RMCs. It is only through such joint African positions that the voice of Africa can be heard and its immense political power demonstrated and respected. The four areas where Africa has demonstrated a strong proactive position vis-à-vis biodiversity are:

- Complete review of TRIPS Agreement.
- Continous monitoring of all patents involving extracts, formulation processes and uses of African plants.
- OAU Model Legislation on Community Rights, Farmers Rights, Access to Biodiversity and Benefit Sharing.
- Implementation of Biosafety Protocol

2.3 INTELLECTUAL PROPERTY ISSUES

The Patent Cooperation Treaty (PCT) was concluded in 1970, amended in 1979 and modified in 1984. PCT is administered by the International Bureau of the World Intellectual Property Organisation (WIPO) which is based in Geneva. All States which are party to the Paris Convention for the Protection of Industrial Property (1883) are eligible to utilize PCT provisions for IPR matters. The Treaty provides for a relatively cheap and convenient way to seek for patent protection for an invention simultaneously in each of a number of countries by filling an international application. In Africa, there are two relevant bodies for patenting of new inventions- African Regional

Intellectual-Property Organisation (ARIPO) for Anglophone countries and OAPI which is the counterpart for the Francophone countries . ARIPO and OAPI are based in Addis Ababa and Yaounde respectively. Both ARIPO and OAPI have functional relationships with WIPO. These bodies on IPR should be contacted by RMCs for advice, guidance, clarification and technical support on all aspects of IPR.

It is strongly advised that new discoveries on the use of formulated medicinal extracts are not published until they are patented with ARIPO, OAPI and WIPO.

3. GLOBAL RESURGENCE IN THE USE OF NATURAL_BASED PRODUCTS.

In the last decade , there was a significant upsurge in the use of natural – based therapeutic products in the developing countries. Various reasons have been attributed to this dramatic change in attitude including the following examples:

- Chronic /incurable diseases (eg autoimmune disorders, arthritis, chronic pains,birth defects, genetic disorders, viral infections, hypertension, diabetes, etc)
- Drug resistant micro-organisms including tuberculosis, fuing, malaria, etc.
- Emergence of new diseases (eg HIV/AIDS, ebola, etc)
- Abundant biodiversity. For example, about 10 years ago, a Smithsonian biologist went to the jungles of Peru on a field trip and concluded that biodiversity on Planet Earth had been underestimated by 90%.
- Recent successful experiences with taxol , artemisinine ,etc.
- Viable choice to consumers amenable to control over quality of life.

TABLE 1: ORIGIN OF THE TOP 150 PRESCRIPTION DRUGS		
NAME	**DRUGS**	**%**
Animal	27	18
Plant	34	23
Fungus	17	11
Bacteria	6	4
Marine	2	1
Synthetic	64	43
Total	**150**	**100**

Source: K. Ten Kate & S. Laird 1999

4. WAYS FORWARD

4.1 ETHNOMEDICAL SURVEYS

Various ethnomedical surveys have been sponsored by OAU/STRC, UNIDO, ROCHE, WHO-AFRO, among others, targeting different ecological zones and countries. Inspite of these efforts, most of the African indigenous medical knowledge is still undocumented. Thus, aggressive ethnomedical surveys sponsored by OAU/STRC and WHO-AFRO will enable the development of African Traditional Medicine database which should not be available on the public domain but rather only accessible to government authorities . Even in such a case , only the data relating to a particular country can be accessed by such a country. The ethnomedical surveys should be disease-driven. Already WHO-AFRO has identified five priority diseases in Africa: HIV/AIDS, malaria, sickle cell anaemia, hypertension and diabetes. Thus, the emphasis of the surveys should be to document recipes used for the management of these priority diseases.

4.2 CLINICAL OBSERVATIONAL STUDIES.

Clinical observational studies involve the observation of patients who voluntarily attend THPs clinics for treatment. Such patients are first screened to confirm their diagnosis while they are also accessed clinically by OMPs. The THP then attend to the patients . After treatment by the THP, the patients are accessed again to confirm if they have been treated. The safety of the products is noted. The data from such observational; studies will indicate whether it is justifiable to continue with the research and development of the product. The clinical observational studies will facilitate the development of standardized phytomedicines.

4.3 COLLABORATION WITH TRADITIONAL HEALTH PRACTITIONERS (THPs) .

It has been observed that many genuine THPs are reluctant to release indigenous knowledge about the use of medicinal plants. They are concerned about possibility of losing ownership of the indigenous medical knowledge. In order to foster a functional collaboration with THPs, it is essential to consider a legal agreement similar to that used by the National Institute of Pharmaceutical Research and Development (NIPRD).

Infact in December 2000, WHO-AFRO adopted the legal agreement used by NIPRD for collaboration with THPs for use by member countries after appropriate modifications.

4.4 BIOGUIDED FRACTITIONATION

Bioguided fractionation of the crude extract using various solvent systems will enable the identification of the bioactive fraction/s . In the efficacy studies, such fractions are used in the test experiments while the total crude extracts are given to the control group. In some cases, the total crude extract may possess the biological activity. Even in such cases, bioguided fractionation will confirm the active fraction. It should be emphasized that whichever fraction is bioactive, should also be subjected to toxicological screening.

4.5 TOXICOLOGICAL EVALUATION.

The bioactive fraction should be evaluated for toxicological profile using repeated effective dose and also establishing the maximally tolerated doses in two rodents.

4.6 STANDARDISATION

The quality of the phytomedicine can only be guaranteed if the plant raw material, processed raw material, formulated phytomedicine, process technology and the environment are appropriately standardized. Botanical identification is crucial to the quality of the finished product. The cultivation techniques should be uniformly maintained using Good Agricultural Practice while harvesting of the desired parts should be done at particular periods in accordance with Good Harvesting Practice. Post-harvesting techniques including drying, cleaning, grinding, storage, etc , should be standardized for all batches. Macroscopic and microscopic characteristics should be used to ascertain the quality of the plant raw materials. Chemical standardization using fingerprinting (with the aid of HPLC or UV) is crucial to confirm consistent chemical integrity of the raw material. Biological standardization using a simple bioassay is necessary for evaluating the bioactivity of each batch. Appropriate use of the WHO Quality control specifications of herbal medicines is strongly advised. The pharmaceutical technical properties of the formulated product should be consistent with all batches. The principles of WHO Quality Standards in Basic Biomedical Research as well as Good Laboratory Practice should be adopted in all the standardization procedures.

4.7 CULTIVATION AND CONSERVATION OF MEDICINAL AND AROMATIC PLANTS.

One of the major constraints regarding the development of herbal medicines is regular supplies of the required quantities and the desired quality of the plant raw materials. The general approach is to conserve the plants in the wild so as to maintain the environmental integrity while the plants required for production of herbal medicine are cultivated both *in situ* and *ex situ.* Unfortunately in most countries, the current practice is to collect the plants from the wild (i.e. wild crafting) which inevitably leads to the depletion and

possible extinction of the plant. Furthermore, increased human activities including bush burning, deforestation for farming purposes, urbanization of the country side and aggressive development of tourism sites around reserves without due regards to the natural habitat may contribute to the extinction of valuable medicinal plants and subsequently permanent loss of rich genetic material. Another problem associated with wild crafting is the non-uniformity of plant material collected at the same time within the same general location due to changes in soil chemistry, weather, human interventions, etc.

In these circumstances, cultivation is the only guarantee to the sustainable supplies of plant materials in the quantities and consistent qualities required for formulation into standardized dosage forms. It may also be possible to develop high yielding varieties with respect to the bioactive moieties using micro propagation like tissue culture techniques.

Since 1978, the Indonesian government introduced the Family Medicinal Garden Movement (FAME project) so as to encourage the indigenes to sensibly utilize valuable medicinal plants which they grow and nurture in their gardens of one or more hectares. Since the the health status of the family is partly dependent on such gardens, the owners take them quite seriously. They also generate the much needed income which can be wisely invested in the education of the children and meeting other social needs of the family. The most widely used medicinal plants required for treating the common diseases are included in the FAME project. Examples include fevers, cough, common cold, stomach upset, nausea, vomiting, dyspepsia, diarrhoea, headache, worm infestations, etc. Thus, a lot of the available land is used for green commercial purposes. In South Africa, commercial farmers are engaged to cultivate specific plant species. The farmers use modern facilities for mechanized farming , drying and milling gadgets. The farmers are able to cultivate large hectares of the desired plants. Thus, they are able to supply regularly large quantities with consistent quality of the desired plant species . Such farmers cultivate in accordance with Good Agricultural Practice, Good Harvesting Practice, Good Post-Harvesting Practice etc.

Regional member countries may use both methods for cultivating the desired plants or provide the enabling environment for investors to cultivate.

4.8 PATENT, OWNERSHIP AND BENEFIT SHARING.

It is important that all new discoveries relating to indigenous medical knowledge are protected through patents, trade secrets , etc . The cost for such protection is usually beyond the researchers and the THPs. Thus, OAU, governments and United Nations agencies have to assist in funding such activities. Collaboration agreements should be devised to legalise the relationship between biomedical researchers and THPs which among others, will indicate ownership of new discoveries, royalties and initial lumpsome payment for valuable information on medicinal plants. It is essential to ensure that the traditional systems and cultures are not disrupted by the wholesale importation of concepts and methods from outside, no matter how seemingly benevolent or well-intentioned. Local knowledge should be used for local self-reliance through equitable distribution of benefits and should result in an overall development of the community. It is relevant to consider the establishment of adequate and sustainable technological platforms in countries rich in biodiversity that allow their genetic resources to be enhanced through material processing and product development.

It is pertinent to mention that in 2000, the OAU adopted an African Model Legislation for the protection of the Rights of Local communities, Farmers and Breeders and for the Regulation of access to Biological Resources. The main aim of this legislation shall be to ensure the conservation , evaluation and sustainable use of biological resources including agricultural genetic resources and knowledge and technologies in order to maintain and improve their diversity as a means of sustaining all life support systems. Regional Member Countries are advised to implement the model legislation and provide the resources for its enforcement and monitoring.

4.9 RANDOMIZED, CONTROLLED CLINICAL TRIALS.

The biomedical scientists argue that it is not feasible to register a herbal preparation for public use without clinical data for efficacy and safety which can only be accumulated through randomized , controlled clinical trials. They argue that any herbal medicine may contain 10 to 100 chemical entities with diverse pharmacological effects on various organs and tissues. A patient may have one of his systems already compromised. Such clinical studies will, among others, involve standard laboratory investigations on blood chemistry, haematology, kidney and liver function enzymes to explore possible side effects and toxicity. The situation is further complicated by the fact that in most cases, a patient may combine two or more herbal medicines with each other or combine orthodox medicine with a herbal preparation. Such combination therapies are potentially dangerous to the patient. The biomedical scientists argue that unless there are controlled clinical trials, it is not possible to predict the consequences of such herbal-orthodox or herbal-herbal medicine interactions.

Furthermore, a proper clinical trial will establish among others, the minimal effective dose, maintenance dose and the tolerable dose as well as the most appropriate dosage regimen. It is also possible to establish some indications which can preclude the herbal medicine from being given to some patients. Sometimes the efficacy of a herbal product is taking for granted because the patient's subjective assessment of his health has improved. Controlled clinical trials will indicate human efficacy of the herbal product. The control group should be treated with a standard , approved orthodox medicine.

These arguments notwithstanding, there is an overwhelming need to ensure that any herbal medicine introduced to the market can be guaranteed to be safe, efficacious and of consistent quality. The consumers have placed their trust in the government vis-à-vis the safety and efficacy of all medicines approved for public use. That trust must not be abused and taking lightly. The government regulatory authority has the sacred responsibility to carry out their duties with utmost sense of care, efficiency and urgency. The ethical emphasis is the health of the volunteer patient who needs to consent to participating in the study after the investigator has explained all the

proeedures, risks and benefits of the new medicine. The study must be conducted in accordance with Helsinki Declaration. Assistance from WHO may be needed regarding the development of appropriate clinical protocols which will be realistic in respect of African situation, relatively cheap and yet will enable the generation of quality and reliable clinical and laboratory data.

4.10 REGISTRATION OF AFRICAN TRADITIONAL MEDICINES.

If the laboratory and clinical data conform with the acceptable national requirements, then the new herbal medicine can be registered by the appropriate government regulatory agency. The WHO-AFRO recently prepared document for the classification and registration of herbal medicines. This model document is available to member countries for their adoption and application. WHO-AFRO can also be consulted for additional guidance on this issue.

4.11 LOCAL PRODUCTION OF AFRICAN TRADITIONAL MEDICINES.

It is expected that once the herbal product has been subjected to controlled clinical trial, it will be registered in the country of origin in the National List of Essential Herbal Medicines for use in the public health sector. If the product needs to be prescribed before use, then it will be marketed as such. At this stage , it will be appropriate to license the product to a manufacturer who will have to pay a lumpsome amount which has to be negotiated as well as agreed royalties on net sales of the product. Since most of the Regional Member countries lack experts in this field, it is recommended that OAU, WHO-AFRO and ARIPO/OAPI (and possibly WIPO) should assist researchers and THPs on this critical issue.

Once the technology has been effectively transferred to the private sector, it is the responsibility of the government to provide an enabling environment for the local production of the phytomedicine. Examples include tax breaks, allocation of adequate size of land for cultivation, processing and manufacturing of the phytomedicine. Furthermore, infrastructural facilities and services should be provided by the government to encourage entrepreneurs to engage in business

ventures including water supply, electricity supply, innovative investment catalysts, access to foreign exchange, tax incentives, among others. The marketing of the product should be regulated in accordance with the applicable national and international regulations.

4.12 POST-MARKETING SURVEILLANCE

It is absolutely essential that as soon as the herbal medicine is launched that a post-marketing surveillance (phase IV) study commences. WHO-AFRO will soon draft model protocol for phase IV study which can be adopted by member countries, investors and researchers appropriately. The main objective of the study is to document all expected and unexpected effects (both beneficial and adverse) of the new herbal medicine. It is possible to identify new uses , limitations and contra-indications for the herbal medicine during such a study. In order to ascertain that the investor carries out this study, it is recommended that it should be included in the provisions of the Licensing Agreement.

4.13 KEY ELEMENTS IN THE SUSTAINABILITY OF AFRICAN TRADITIONAL MEDICINE INDUSTRY.

Promotion of this sector can be sustained if there is political will on the part of the governments of the African region to ensure that the enabling environment is created. Examples include appropriate legislation, access to loans, tax breaks, credit for investors band a commitment to register and use proven herbal medicines. The THPs have significant roles including their willingness to enter into partnership with researchers and investors. In such cases, appropriate legal documents with unambiguous provisions on the royalties, benefit sharing formulae, responsibilities and rights of the parties, etc. will facilitate the implementation of the project. Furthermore, clauses on the perpetuity of the benefits derivable from such partnerships will enhance the full co-operation of the THPs. Government will generally serve to protect the interest of the community and the THPs in addition to ensuring that the framework for monitoring the various activities are well established while the resources for the government agency charged with such responsibility are provided at the right times.

Cultivation of the desired plant species is mandatory for the sustainability of this activity. In fact, the raw plant materials constitute the most critical factor in sustaining the business. It is therefore significant for the government to legislate appropriate laws which will enhance access to large hectares of land for the cultivation of valuable medicinal plants. Once the rural farmers are adequately encouraged to participate in the cultivation , they will easily realize the economic potentials of the activity which will facilitate their continued participation. Such medicinal plants will soon be regarded as valuable economic plants.

It is even possible to assist farmers to start the medicinal plant farms by providing them with the materials and resources required for them to commence the farm. Thus, the plants will belong to them while the harvested parts of the plants are sold to the investor. The farmers can repay the loans (no interest) using a convenient payment schedule. The renewable nature of the raw material is a unique advantage in this business. Infact, it offers a competitive advantage over synthetic drugs which rely on fossils and petro-chemicals for their basic raw materials. Such raw materials , unlike plants, are not renewable . This competitive advantage will facilitate the sustainability of the herbal medicine industry.

5. RECOMMENDATIONS

5.1 POLICY IMPLEMENTATION.

2001-2010 , THE DECADE FOR AFRICAN TRADITIONAL MEDICINE as declared by OAU is a historic political declaration and commitment. WHO-AFRO has developed the following model documents:

- Guidelines on the formulation, implementation and evaluation of national policy on traditional medicine.
- Model Traditional Medicine Bill for the practice of traditional medicine in the WHO African Region.
- Model Code of Ethics for traditional health practitioners in the African region.
- Framework for registration of traditional medicines in the WHO African Region.

- Framework for the protection of intellectual property rights and indigenous knowledge in the WHO African Region.
- Proposed methodology for documenting African traditional medicine in the Region.

OAU/STRC should endeavour to work closely with WHO so as to adopt these draft documents for the regional member countries for effective implementation and guidance. The objective in this decade is to assist most member countries to establish legal framework for the practice of traditional medicine and also institutionalize traditional medicine by socio-political structures in appropriate departments/ministries of government.

5.2 ETHNOMEDICAL SURVEYS

In view of the fact that most THPs with credible indigenous medical knowledge are elderly members of the African society, OAU/STRC should consider the support for ethnomedical surveys as priority activity in the next five years. Such surveys should cover different ecological zones while the data accumulated from the surveys should be treated as confidential document. OAU/STRC should identify conditions for guiding the countries/communities who own the knowledge regarding release of the data to any organization.

5.3. COLLABORATION WITH TRADITIONAL HEALTH PRACTITIONERS (THPs)

The THPs should be involved in all aspects of the research and development of ATMs. Equitable benefits sharing formulae should be discussed with THPs and agreed possibly through a legal agreement. The THPs should be considered as equal partners. OAU/STRC may consider the draft WHO legal agreement with THPs.

5.4. NETWORKS

The International Development Research Centre (IDRC) has proposed the networking of various research institutions and researchers in the African region for information sharing which will facilitate collaboration and development of standardized herbal medicines. Indigenous medicinal plants grow naturally across political boundaries. Research and Development facilities vary among various member countries. Networking will enable

joint research projects to be implemented utilizing the facilities and expertise of countries with the joint collaborations. IDRC should work closely with OAU/STRC to realize the laudable goals of such networking within the next three years.

5.3 TRAINING PROGRAMMES

Appropriate training programmes should be developed for researchers and THPs in cultivation, harvesting , IPR issues, licensing agreements, equitable benefit sharing, WHO Good Laboratory Practice, WHO Good Clinical Practice, biodiversity, etc. In order to achieve this objective, OAU/STRC should work closely with WHO, FAO, UNIDO and other UN agencies.

5.5 AFRICAN MODEL LAW FOR THE PROTECTION OF THE RIGHTS OF LOCAL COMMUNITIES, FARMERS AND BREEDERS AND FOR REGULATION OF ACCESS TO BIOLOGICAL RESOURCES.

It is recommended that OAU/STRC should provide technical support to member countries to facilitate the development of national versions of the Model law. It is anticipated that efforts in this direction should manifest in the development of national policies based on the Model Law within the next three years in most member countries.

5.6 PRIORITY DISEASES

In conformity with the identification of five priority diseases by WHO-AFRO on the initial list for African Region, OAU/STRC should consider adopting a similar position. It is recommended that OAU/STRC should support the research and development of herbal medicines targeting these diseases in the next five years. It is anticipated that one herbal product should be developed for each of these priority diseases within the next five years from African Region.

5.7 FUNDS FOR RESEARCH AND DEVELOPMENT ACTIVITIES.

Adequate funds will be required to translate the OAU Declaration into safe, effective , affordable , available and quality African herbal medicines within the next five years. The resources, indigenous medical technology (THPs) and biomedical researchers are available within the African Region to ensure that our objective is realized. Adequate funds may constitute the main obstacle. It is recommended that OAU/STRC should work closely with WHO-AFRO, ADB , bilateral and multilateral modalities to map out the mechanisms for generating funds to enable African researchers and THPs develop standardized African herbal medicines within the next five years.

5.8 CONTROLLED CLINICAL TRIALS

Controlled clinical trials conducted in two or more member countries concurrently should be encouraged. Such an approach will facilitate the registration and availability of African standardized herbal medicines in member countries and also reduce the cost of conducting the trials separately in such member countries. It is recommended that both OAU/STRC and WHO-AFRO should support such proposals among their priorities.

5.8.1. LOCAL MANUFACTURE OF AFRICAN TRADITIONAL MEDICINES

Unless the standardized African traditional medicines are manufactured in commercial quantities in accordance with Good Manufacturing Practice principles, such products can not be used in the public health sector. Both OAU/STRC and WHO-AFRO should work closely to guide member countries vis-à-vis creation of the enabling environment to facilitate the establishment of industries by investors for the local manufacture of standardized African traditional medicines.

6. CONCLUSION

We are privileged to witness an exciting period in the political recognition of African Traditional Medicine. The Declaration of the Decade of African Traditional Medicine by the Organisation of African Unity (OAU) has also posed challenges at all the stakeholders in this field, especially in Africa. It

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