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DRAFT FINAL REPORT

Workshop on

"Strategies To Strengthen The Utilisation of MAPs In The National Health Care System"

Place: Abuja, Nigeria

Date: 11- 13 July, 2000

Organised by

ICS – UNIDO

in collaboration with

National Institute for Pharmaceutical Research and Development (NIPRD), Idu, P. M. B. 21, Garki – Abuja, Nigeria.

STRATEGIES TO STRENGTHEN THE UTILISATION OF MAPS IN THE NATIONAL HEALTH CARE SYSTEM

ICS-UNIDO/NIPRD WORKSHOP, 11 – 13 JULY 2000, ABUJA, NIGERIA

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BACKGROUND

Great advances have been made in the therapeutic arsenal of conventional medicines. However, there is still a great reliance on traditional medicine by a major section of the society especially in developing countries. Therefore the benefits of such giant strides are not felt by the poor of developing countries.

Even in western countries, there is an increasing interest in the use of Medicinal and Aromatic Plants (MAPs). This trend is due to the awareness of the effectiveness of traditional medicines over and above orthodox medicines used for the management of chronic ailments like Rheumatism, Diabetes, Hypertension, Sickle-cell anaemia, Cancers, etc. In addition, Africa's flora is a rich reservoir for new molecules which can be tapped in the discovery of new drug molecules. This has the economic advantage of combating the high cost of research on the discovery of new drugs. Major pharmaceutical houses have on-going research programmes to discover potential molecules from natural resources.

In another vein, medicinal plants are more accessible and cheaper than western drugs to majority of people in developing countries. Their mode of use is acceptable to the majority. Moreover cultural beliefs associated with their use enhances the popularity of Traditional Medicine (TM) in developing countries. Experiences of the health benefits of the use of TM also abound in societies of developing nations.

Developing and western nations thus have a mutual interest in medicinal plants. However, developing nations cannot foray into research on the discovery of new drugs because of economic constraints and lack of adequate infrastructural facilities. Therefore they will greatly benefit from the provision of scientific bases for traditional medicines.

JUSTIFICATION

This situation presents a challenge to developing countries to gear themselves to meet the demands of the emerging world pharmaceutical market. Most of these countries have ample resources and proven strong traditions which have endured through centuries for the use of alternative medicines. Therefore they should direct their efforts at consolidating traditional knowledge to produce plant-based drugs for local consumption in order to meet the health care needs of their people.

With the awareness that traditional remedies are a potential reservoir of new potent drugs, efforts should be made to document all the available information on traditional medicines in order to prevent exploitation by the Western pattern of patenting. There is also the need for an initiative for discussing ways to integrate the use of traditional medicines with modern ones in order to conserve financial resources and achieve the goal of health for all. Member countries should be encouraged as a matter of priority to invest in the mandatory safety and clinical efficacy investigation of herbal medicines while appropriate regulations are established for the integration of such proven medicines.

OBJECTIVES

The workshop has the following objectives:

1. To conduct brainstorming sessions to discuss present world trends and define strategies to promote relevant issues for integrating traditional medicines in state health programmes.

2. To discuss relevant issues for targeted strategies to promote safe use of traditional medicines in developing countries especially in Africa and to increase awareness of policy makers.

3. To propose strategies to document, validate and evaluate the safety of folk remedies.

4. To discuss research programmes suited to the needs of these countries in order to provide safe medicines at affordable prices.

5. To recommend suitable measures for ensuring the availability of medicinal plant materials for future generations.

OUTPUTS

The workshop is expected to outline the direction of research in medicinal and aromatic plants in order to strengthen their use in traditional medicines; provide guidelines to encourage the state use of traditional medicines and render help to developing countries in improving their health care systems and conserving financial resources which would normally be expended on modern medicines in instances where traditional remedies could be equally effective. Accordingly, the workshop's outputs are as follows:

Direction for Research

Each developing nation should identify its priority disease out of those identified by WHO-AFRO for developing regions namely Malaria, HIV-AIDS, Hypertension, Sickle Cell anaemia and Diabetes.

Emphasis on MAPs research should be on formulation studies, pilot and large-scale production of the appropriate MAPs for the identified priority diseases, and controlled clinical trials for the safety and efficacy investigations of such products.

Each developing country should prepare a database of its research findings on MAPs for application at national and international levels for the benefit of humankind.

WHO-AFRO and ICS should facilitate the use of their websites to help developing nations prepare their databases on MAPs and to ensure the exchange of existing and new databases.

Developing nations should conduct public enlightenment campaigns in order to create better awareness of Traditional Medicine (TM) in the public, policy makers and pharmaceutical industry.

Training programmes should be conducted in recognised institutions for Traditional Medical Practitioners (TMPs) through the training of the trainers with a view to improving their skills in formulating herbal preparations and ensuring the quality, safety and efficacy of such preparations.

Training programmes on TM should be established in existing relevant institutions of higher learning with a view to eventually establishing separate training institutions for TMPs.

Introductory lessons to MAPs should be included on the Biology/Nature Study syllabus for secondary and primary schools respectively.

Furthermore, short-term courses on TM should be included in the curriculum of doctors, pharmacists and nurses.

ICS and UNESCO, in collaboration with WHO-AFRO, should organise a workshop for selected experts to produce a curriculum on teaching MAPs for teacher training colleges.

Guidelines for State's Use of Traditional Medicines

Each country should establish regulations for registration requirements for herbal medicinal products as has been done in Nigeria and Ghana.

Since the biodiversity of many MAPs is endangered in that many of them are collected from the wild at present, each country should encourage good harvesting procedures for MAPs in the wild, the commercial cultivation of MAPs and the creation of home gardens and arboreta. In addition the quality of the raw material must be ascertained for each batch collected for processing while the post-harvest processing must be properly controlled for consistency. *In-situ* and *ex-situ* conservation of valuable MAPs should be encouraged and supported by member countries utilising the guidelines of good agricultural practices.

Each country should promote the use of Biotechnology, with other conservation techniques such as gene banks, as a technique in propagation and conservation of MAPs.

Each country should endeavour to utilise existing information on MAPs which are available in developing countries and which are documented in Ayurvedic Indian Medicine, Chinese Materia Medica and in other pharmacopoeias.

Each country should enact appropriate national legislations with regards to the knowledge of TMPs and rural communities with a view to protecting such as their intellectual property in accordance with the provisions of article 8(j) of the Convention of Biodiversity (CBD).

Assistance in Improving Health Care & Conserving Financial Resources

Developing nations should give incentives to entrepreneurs and pharmaceutical companies in forms of tax reliefs, soft loans and land lease to encourage plant-based pharmaceutical production.

Training fellowship exchanges should be granted to young scholars from developing countries to study Ayurvedic, Chinese and other MAP-based systems of medicine. Also study tours and exchange of scholars and practitioners should be facilitated between member-countries.

Funding agencies should provide developing nations with appropriate network arrangements, individual initiatives, private ventures and partnerships with international organisations which will strengthen the utilisation of medicinal and aromatic plants.

RECOMMENDATIONS

THE ABUJA DECLARATION: AN AFRICAN APPEAL FOR THE UTILISATION OF MEDICINAL AND AROMATIC PLANTS ABUJA, 13 JULY 2000

Preamble: We, the participants gathered in Abuja, Nigeria from 11 – 13 July 2000, on the occasion of a workshop organised by International Centre for Science and High Technology (ICS-UNIDO) in collaboration with National Institute for Pharmaceutical Research and Development (NIPRD) on "Strategies To Strengthen The Utilisation of MAPs In The National Health Care System", examined ways to strengthen the use of Medicinal and Aromatic Plants (MAPs) in the health care system of developing countries and declare the following:

Recognising the tremendous advances made in the therapeutic arsenal of conventional medicines.

Concerned that the benefits of such advances are still unfelt by the poor especially in developing countries.

Acknowledging that the major section of society in developing countries still rely on traditional medicines for their health care.

Recognising the renewed interest in medicinal plants as a preferred option in the western world as a result of which traditional medicine is receiving increasing attention from international health bodies.

Aware that major pharmaceutical houses have ongoing research programmes to discover potential molecules from natural resources.

Convinced that medicinal and aromatic plants have great potentials to provide novel drug molecules for the treatment of both acute and chronic diseases.

Concerned that the huge financial cost involved has made research on new drug molecules the exclusive domain of developed countries and the forbidden terrain for developing nations.

Concerned further that, since expected economic returns are a driving factor in defining the research directions of pharmaceutical houses, the patent structure of the new drugs will further force poor nations to use more money to buy expensive drugs to meet their citizens' health care needs.

Affirm that strengthening the use of traditional medicines by providing them with scientific bases is well within the ambit of developing countries.

We, the participants, therefore:
Pledge to use our individual and corporate expertise and commitment to strengthen the use of MAPs in the health care system of developing nations.

Urge each developing nation to identify its own priority diseases out of those identified by WHO-AFRO for developing region namely Malaria, HIV-AIDS, Hypertension, Sickle cell anaemia and Diabetes.

Further urge the national governments of developing countries to give incentives to entrepreneurs and pharmaceutical companies in forms of tax reliefs, soft loans, and land lease to encourage plant-based production.

Reiterate the need for training programmes in recognised institutions for Traditional Medical Practitioners (TMPs) through the training of the trainers with a view to improving their skills in formulating herbal preparations and ensuring the safety/efficacy of such preparations.

Further reiterate the need for the establishment of training programmes in existing relevant institutions of higher learning with a view to eventually establishing separate training institutions for TMPs.

Recommend that introduction to MAPs should be included on the Biology/Nature Study syllabus for secondary and primary schools respectively and that short-term courses on Traditional Medicine (TM) should be included in the curriculum of doctors, pharmacists and nurses.

Appeal to ICS and UNESCO in collaboration with WHO-AFRO to organise a workshop for selected experts to produce a curriculum on teaching MAPs for teacher training colleges.

State that, given the available research information on MAPs, henceforth, emphasis on MAPs research should be on formulation studies, pilot and large scale production of the appropriate MAPs for the identified priority diseases and controlled clinical trials for the safety and efficacy of such products.

Appeal to each developing country to prepare a database of research findings on MAPs for application at national and international levels for the benefit of humankind.

Further appeal to WHO-AFRO and ICS to facilitate the use of their websites in this regard and to assist in ensuring the exchange of existing and new databases on MAPs.

Recommend that each country should establish regulations for registration requirements for herbal medicinal products as has been done in Nigeria and Ghana.

Note that the biodiversity of many MAPs is endangered in that many of them are collected from the wild at present.

Encourage good harvesting procedures for MAPs in the wild, the commercial cultivation of MAPs and the creation of home gardens and arboreta.

Urge developing nations to conduct public enlightenment campaigns in order to create better awareness of TM in the public, policy makers and pharmaceutical industry.

Recommend that appropriate national legislations be enacted with regards to the knowledge to TMPs and rural communities with a view to protecting such as their intellectual property in accordance with the provisions of article 8(j) of Convention of Biodiversity (CBD).

Affirm the importance of Biotechnology, with other conservation techniques such as gene banks, as a technique in propagation and conservation of MAPs.

Urge that efforts should be made to utilise existing information on MAPs which are available in developing countries and which are documented in Ayurvedic Indian Medicine, Chinese Materia Medica and in other pharmacopoeias.

Further urge that young scholars from developing countries should be granted fellowship exchanges to study Ayurvedic, Chinese and other MAP-based systems of medicine.

Appeal to funding agencies to provide appropriate network arrangements, individual initiatives, private ventures and partnerships with international organisations in order to achieve these recommendations.

IMMEDIATE FOLLOW-UP

In line with the initiative of Professor Ermias Dagne of Ethiopia who prepared the database of research publications on MAPs of Africa, each country will prepare a database of its research findings on MAPs with a view to creating a network for a mutual sharing of databases with other nations for the benefit of humankind.

Extensive public enlightenment campaigns will be carried out on the benefits of medicinal and aromatic plants with a view to creating better awareness of their use.

Regulations and protocols for registering herbal medicinal products will be established by each developing nation.

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AIDE-MEMOIRE

Workshop on "Strategies to Strengthen the Utilization of MAPs in the National Health Care System"

Abuja, Nigeria
11-13 July, 2000

organized by

ICS-UNIDO

in collaboration with the

NATIONAL INSTITUTE FOR PHARMACEUTICAL
RESEARCH AND DEVELOPMENT [NIPRD]

BACKGROUND

Despite tremendous advances made in the therapeutic arsenal of conventional medicines, its benefit is still unfelt in the poor section of society. The major section of society, especially in developing countries continue to rely on traditional medicines to meet their health care needs. Economical considerations are more important than any other factor to deprive people in developing countries of the benefit of modern medicines. Whereas, the use of traditional systems of medicine and medicinal plants is compelling factor in poor nations it has become a preferred option of the western World. The reasons are different for using plant based medicines by these two sections which are on two extremities of economical status. The prevailing situation in developed and developing countries has renewed with great fervour the interest in medicinal plants. Traditional medicines are receiving greater attention of international health bodies in an effort to confront the high cost of modern drugs to achieve health for all. The potential of medicinal plants to provide novel drug molecules has been more appreciated in recent years than ever before. All major pharmaceutical houses now have ongoing research programmes to discover potential molecules from natural resources.

Research in discovery of new drug molecules has become the domain of developed world. The spiralling cost incurred in discovering a new drug entity forbids the entry of developing world in this arena. However, strengthening the use of traditional medicines by providing scientific basis is well within the ambit of developing countries. The new patent structure will further harm economically weaker nations, who will be forced to shed more money to buy expensive drugs to meet health care needs of their people.

The expected financial return is a driving factor to define research direction of pharmaceutical houses. The poor nations are left to their mercy for specific health problems in these countries, as multinational houses will never consider it their priority.

JUSTIFICATION

It is certain in this situation that developing countries are to gear themselves to meet the challenges of merging word market. The increasing cost of modern drugs coupled with limited available resources in developing countries, especially in Africa, make it mandatory that efforts should be directed to consolidate traditional knowledge to produce plant based drugs for local consumption. These countries are to design strategies, which are suited to meet health care needs of their own people. Fortunately, most of the developing countries have strong traditions and resources of using alternative medicines, which have perpetuated through centuries. Immediate validation of these remedies should be an immediate priority. Once the safety and efficacy of herbal medicine is established, it can be easily integrated in state health care programmes.

The traditional remedies are also seen as a potential reservoir of new potent drugs. That necessitates documenting all the available information of traditional remedies to prevent its flaying by western trend of patenting. All said is not so simple, but serious efforts need to be made in this direction. The success stories of China and India can be analysed as role models. These countries which had strong system of traditional medicines also had the advantage of well-documented

information. They have successfully integrated the alternative systems with modern medicines.

The present workshop is an initiative for discussing strategies to strengthen use of alternative medicines in countries rich in biodiversity and traditions of using medicinal plants. The workshop will also discuss ways to integrate traditional medicines with modern ones to achieve the goal of 'health for all' and also to save state exchequer.

OBJECTIVES

There is still insufficient knowledge on traditional medicines and their limitations and prospects. There are no clear-cut policies on sustainable use and conservation of medicinal plants. Most African countries lack national policies on access to genetic resources and trade in medicinal plants, which has resulted in threat to resources that are otherwise essential for sustaining local population. This workshop has been called to provide answers to number of questions that are raised in narrowing the gap between traditional and modern medicines. The workshop will give the opportunity to experts working in the area of medicinal plants to have brainstorming sessions to discuss the present world trends and define strategies to promote and integrate traditional medicines in state health care programmes. The workshop will discuss relevant issues for targeted strategies to promote state use of traditional medicines in developing countries, especially in Africa and to increase awareness of policy makers. The research strategies to document, validate and evaluate safety of folk remedies will be discussed. The recommendations of the workshop will serve as guidelines for national policy makers. The Workshop will also discuss research programmes suited to the needs of these countries to provide safe medicines at affordable price. The issue of threat to biodiversity of medicinal plant resources will be discussed to recommend suitable measures to ensure availability of medicinal plant materials for future generations.

EXPECTED OUTPUTS

The workshop is expected to outline the direction for research in medicinal and aromatic plants to strengthen their use in traditional medicines. The recommendations of the workshop will provide in place guidelines to encourage the state use of traditional medicines. The workshop will render help to developing countries in not only improving their health care systems but also saving spendings on medicines for which traditional remedies could be equally effective.

STRUCTURE AND MAIN TOPICS OF THE WORKSHOP

The workshop will consist of presentations and round table discussions.

The following topics will be discussed at the workshop:

- Scope and role of traditional medicines in health care systems of developing countries.
- Challenges, constraints and opportunities in traditional medicines in the African continent.
- The successful examples from different countries.
- The present trends in medicinal plants research. Future research needs and challenges of developing nations.
- Ethno-pharmacological investigations and production of drugs from medicinal plants.

The topics related to: documentation, validation and safety evaluation of traditional medicines, production of standardized herbal drugs, issues of biodiversity conservation and production opportunities of medicinally important plants, medicinal plants in African continent, will also be discussed during the workshop.

PARTICIPATION

The workshop will be attended by experts from drug industry, research institutes and bodies involved in research and development of drugs from medicinal plants. Experts working in traditional medicines and designing health policies of states will also be invited. The workshop will focus more on African continent but experts from other developing and developed countries will be invited for pooling of update information on the subject.

DOCUMENTATION

The documents available for the training course will be:

1. Aide-Mémoire of the Workshop.
2. Programme and list of participants.
3. Lecture notes.

LANGUAGE

The Workshop will be conducted in English and no translation facilities will be available. It is expected that the participants have a good command of English.

TIME AND VENUE

The Workshop will be held at the ...NIPRD.. in Abuja, Nigeria from 11 to 13 July 2000.

FINANCIAL ADMINISTRATIVE ARRANGEMENTS FOR UNIDO-ICS FINANCED PARTICIPANTS

For those who will be invited by UNIDO-ICS to participate in the Workshop, round-trip air-economy transportation from the airport of departure will be arranged and prepaid tickets issued where necessary by the local organizers.

A daily allowance in local currency sufficient to cover board and lodging will be provided upon arrival to Abuja for the period of attendance to the meeting. Reservations will be made for all participants at the same hotel upon request.

The participants will be required to bear the following costs:

All expenses in their home country incidental to travel abroad, including expenditures for passport, visa, and any other miscellaneous items. UNIDO-ICS will not assume responsibility for any of the following costs, which may be incurred by the participant while attending the meeting:

1. compensation for salary or related allowances during the period of the workshop;
2. any costs incurred with respect to insurance, medical bills and hospitalization fees;
3. compensation in the event of death, disability or illness;
4. loss or damage to personal property of participants while attending the workshop.

VISA ARRANGEMENTS

Participants are requested to arrange for their visa as early as possible at the Nigerian Embassy in their home country. In case of difficulties, please advise the contact person mentioned below.

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PROGRAMME

WORKSHOP ON "STRATEGIES TO STRENGTHEN THE UTILISATION OF MEDICINAL AND AROMATIC PLANTS IN THE NATIONAL HEALTH CARE SYSTEM" ABUJA, NIGERIA, 11 - 13 JULY, 2000

MONDAY 10 JULY 2000

ARRIVAL

TUESDAY 11 JULY 2000

9.00 – 10.00	**REGISTRATION**
10.00 - 11.30	**OPENING CEREMONY**
	National Anthem Address by Director-General/Chief Executive of NIPRD
	Introduction of ICS by Scientific Consultant, Earth, Environmental and Marine Science and Technologies (ICS-UNIDO).
	Address by the Special Guest of Honour: the Honourable Minister of State, Federal Ministry of Science and Technology (FMST)
	Vote of Thanks
11.30 - 11.45	**Coffee Break**

SCIENTIFIC SESSIONS

11.45-12.45: **SESSION 1:**
"The Role of Medicinal and Aromatic Plants for the Health Care Needs of Developing Countries" (Prof. Baser).

12.45-13.15: **SESSION 2:**
"Regulatory Considerations of Herbal Medicines" (Prof. Sokomba).

13.15-13.50: GROUP DISCUSSION

13.50-14.35: GROUP LUNCH

14.35-15.35: **SESSION 3:**
"Challenges, Constraints and Opportunities in Traditional Medicine in Africa" (Prof. Sofowora).

15.35-16.35: **SESSION 4:**
"Indian Experience of Utilisation of Medicinal Plants and Traditional Aryuvedic Medicine in National Health Care System" (Dr. Sharma)

16.35-17.00: **DISCUSSION**

17.00-17.15: COFFEE BREAK

17.15-17.40: **SESSION 5:**
"Present Trends in Medicinal and Aromatic Plants Research: An African Perspective" (Dr. Dagne).

17.40-18.10: SESSION 6:
"Ownership and Sustainability Issues of Herbal Medicines" (Prof. Gamaniel).

18.10-18.30 DISCUSSION

WEDNESSDAY 12 JULY, 2000.

9.00-9.20 **SESSION 7:**
"Process Technology for the Extraction of Medicinal/Aromatic Plants on a Pilot Scale" (Engr. Amlabu).

9.25-9.50 **SESSION 8:**
"Bio-guided Extraction/Isolation of a Medicinal Plant" (Dr. Enwerem).

9.50-10.20 **SESSION 9:**
"Standardisation of Herbal Medicines" (Dr. Obodozie).

10.20-11.0 **DISCUSSION**

11.00-11.15 **COFFEE BREAK**

11.15-11.45 **SESSION 10:**
"Commercial Production of Herbal Medicines (Dr. Ngoulla).

11.45-12.30 SESSION 11
"Clinical Trials of Herbal Medicines – Challenges and Prospects" (Prof. Wambebe).

12.30-13.0 DISCUSSION

13.00-13.40 GROUP LUNCH

13.40-14.05 SESSION 12
"Improving Plant Medicine for Health Care Delivery in Ghana" (Dr. Nyarko).

14.05-14-.30 SESSION 13:
"Efforts Pursued in South Africa to Strengthen the Utilisation of Medicinal Plants and Traditional Medicine in Health Care System" (Mr. Mayeng).

14.30-15.30 DISCUSSION

15.30-15.45 COFFEE BREAK

15.45-16.0 SESSION 14:
"Promoting the Use of Traditional Herbal Medicines in the Nigerian Health Care System" (Dr. Fakeye)

16.00-16.15 SESSION 15:
"The Integration of Traditional Medicine in the Utilisation of MAPs in the National Health Care System" (Dr. Mhame)

16.15-16.45 DISCUSSION

16.45-17.45 TOUR OF NIPRD'S FACILITY

THURSDAY 13 JULY 2000

9.00-11.15 Round Table Discussion/Recommendations

11.00-11.15 COFFEE BREAK

11.15-12.15 Meeting of Chairs and Rapporteurs to prepare a Communique

12.15-13.30 Presentation and adoption of the Communique

13.30-14.30 Closing Ceremony

14.30-15.00 GROUP LUNCH

15.00-17.00 Sightseeing including a visit to Abuja Market

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SUMMARY OF PAPERS PRESENTED

1.	Prof. (Dr) K. Husnu Can Baser	"The Role of Medicinal and Aromatic Plants for Health Care Needs of Developing Countries"
2.	Prof. E.N. Sokomba	"Regulatory Considerations of Herbal Medicines".
3.	Prof. Abayomi Sofowora	"Challenges, Constraints and Opportunities in Traditional Medicine in Africa".
4.	Dr. S.K. Sharma	"The Indian Experience of Utilisation of Medicinal Plants and Traditional Ayurvedic in National Health Care System".
5.	Dr. Ermias Dagne	"Present Trends in Medicinal and Aromatic Plants Research: An African Perspective".
6.	Prof. Gamaniel I. Shingu	"Ownership and Sustainability Issues of Herbal Medicines".
7.	Engr. Elias N. Amlabu	"Process Technology for the Extraction of Medicinal/Aromatic Plants on a Pilot Scale".
8.	Dr. Nkechi M. Enwerem	"Bio-Guided Extraction/Isolation of a Medicinal Plant".
9.	Dr. Obiageri Obodozie	"Standardisation of Herbal Medicines".
10.	Dr. Mariane Ngoulla	"Commercial Production of Herbal Medicines"
11.	Prof. Charles Wambebe	"Clinical Trials of Herbal Medicines: Challenges and Prospects".
12.	Dr. Alexander I. Nyarko	"Improving Plant Medicine for Health Care Delivery in Ghana".
13.	Mr. Isaac Mayeng	"Approaches Pursued in South

		Africa to Strengthen the Utilisation of Medicinal Plants and Traditional Medicine in the Health Care System".
14.	Dr. Paulo P. Mhame	"The Integration of Traditional and Modern Medicine in the Utilisation of MAPs in National Health Care System".
15.	Dr. Tolu Fakeye	"Promoting the Use of Traditional Herbal Medicine in the Nigerian Health Care System".
16.	Dr. Femi Rabiu	"Expectation of the Industry"

PAPER 1

THE ROLE OF MEDICINAL AND AROMATIC PLANTS FOR HEALTH CARE NEEDS OF DEVELOPING COUNTRIES (Prof. Dr. K. Husnu Can Baser, Turkey)

Traditional systems of medicine have not only provided us with a system to diagnose illnesses and remedies, but also combined plant, animal and mineral drugs to prepare compound medicines.

A recent estimate for the average cost of a successful new drug application in USA is USD 395 million over a period of 20 years. The cost of developing a herbal medicine in Germany in early 1990 was estimated as at least DM 50 million. Such high costs cannot be met by any company unless there is a reasonable expectation that a profit will be gained after the drug marketed. Such a high investment for R & D in Pharmaceutical industry is not at all possible for developing countries. Therefore, they need to devise new ways of developing their own cost effective medicines preferably from plants.

In 1999 the world-wide sale of phyto-pharmaceuticals reached USD 19.6 billion. Europe leads the market, followed by Asia, North America, Japan, Latin America, and Africa + the Middle East and the rest of the world with about 200 million each. The expected growth rate of the phyto-pharmaceutical market in the next two years is expected at around 8-10%. There is a variation of the regulation of these phyto-pharmaceuticals between the USA and Europe and within European countries. To harmonise the regulation in Europe, the European Pharmacopoeia has been charged to prepare monographs (101) with the assistance of an expert committee.

The situation in developing countries is quite different. There is hardly any legislative criteria to establish traditionally used herbal medicines as part of the drug legislation. To assist member states, WHO has developed the following guidelines:

* Guidelines for the assessment of herbal medicines (1991)
* Guidelines for evaluation of the safety and efficacy of herbal medicines (1993)
* Guidelines for formulation of national policy on herbal medicines (1994)
* WHO Monographs on Selected Medicinal Plants (1996)

In Turkey, serious attempts were made in 1985 to regulate herbal medicines by the establishment of a National Registration Committee for Herbal Remedies. Unfortunately, the committee was abolished in 1990. But recently, the Ministry of Health has introduced new regulations for registration of herbal medicines for sale in pharmacies. The general requirements for the manufacture of herbal medicines are:

* Good Quality Plant Materials
* Good Harvesting Practice
* Assessment of the Quality of Herbal Medicine

In conclusion, it is clear that the upsurge of interest in herbal medicines will continue and expand not only in the developing, but in the developed world as well.

PAPER 2

REGULATORY CONSIDERATIONS OF HERBAL MEDICINES
(Prof. Sokomba, Nigeria)

The National Agency for Food and Drug Administration and Control (NAFDAC) is the regulatory authority in Nigeria. The Agency was established in 1993 with the mandate to regulate and control the importation, exportation, manufacture, advertisement, distribution, sale and use of food and drugs including traditional medicines, cosmetics, medical devices, bottled water and chemicals.

Herbal medicinal products are widely used in Nigeria as part of traditional medicine practice. This trend is growing probably as a result of the current unfavourable economic situation in the country. In response to that development, NAFDAC has taken necessary steps to regulate and control the use of these products with a view to ensuring their quality, safety and efficacy. The agency has developed a guideline for regulatory control of medicinal products in Nigeria. This document was recently approved by the National Council on Health.

Some areas are relevant for the development of herbal medicinal products and their regulatory control like:

* Research and development
* Conservation
* Education and training

PAPER 3

CHALLENGES, CONSTRAINTS AND OPPORTUNITIES IN TRADITIONAL MEDICINE IN AFRICA (Prof. Abayomi Sofowora, Nigeria)

Throughout the entire world, interest in medicinal plants has increased tremendously in the past two decades. More than 200,000 out of the 300,000 plant species so far identified in the world are in the tropical countries of Africa and elsewhere. Traditional medicine, the major developing source of medicine for many countries (80% of the population of the third world) relies heavily on these plants and pharmacopoeia.

An overview of research into African medicinal plants shows that a lot has been done in terms of:

Ethnobotanical surveys: This has been conducted by OAU/STRC, ACCT... The results are available in different data bases such as NARISTAN, LEAP, NAPRECA.
Phytomedical and biological screening of medicinal plants: At the OAU conference organised in Dakar in 1968, it was decided that the efficacy of herbs used by traditional practitioners should be tested in order to find proofs for claims of their efficacies. The areas to be given priorities were: anticancer, antimalarial, anti-helminthic, antimicrobial, antihypertensive, cardiac activity, antisickling and antiviral.

Collaboration in R&D on medicinal plants in Africa: Different networks have been created with the support of International Institutions like UNESCO for the creation of the Natural Products of East and Central Africa (NAPRECA), the West Africa Network (NAPRWA). The creation of these networks gave a boost to inter-African collaborative efforts on medicinal plants in that sub-region of Africa.

Inter-African cooperation: The development of the first African pharmacopoeia published in 1985 by OAU/STRC is a good example of inter-African cooperation. Despite all these efforts there is a little production of phytomedicines in Africa.

The constraints and problems identified with respect to industrial utilisation of African medicinal plants are:
Equipment cost; Cultivation; Lack of research equipment; Problems of patenting discoveries; Finding markets; Political instability; The political will; Funding; Extreme reliance on importation to the negligence of indigenous production; inadequate production demonstration units in Africa; Lack of infrastructure; Bias against traditional medicine by some health personnel; Delay in actualising project proposals.

It is very important to strengthen the inter-African and international cooperation in developing the industrial utilisation of African medicinal plants with a view to producing good quality, affordable medicines for Africans.

PAPER 4

THE INDIAN EXPERIENCE OF UTILISATION OF MEDICINAL PLANTS AND TRADITIONAL AYURVEDIC IN NATIONAL HEALTH CARE SYSTEM

(Dr. S. K. Sharma, India)

The ancient civilisation of India, China, Greece, Arab and other countries of the world developed their systems of medicine independent of one another but all of them were predominantly plant-base. Medicinal plants continue to be an important therapeutic aid for alleviating the ailments of humankind. The search for eternal health and longevity and remedies for relieving pain and discomfort prompted the early man to explore his immediate natural surrounding-plants, animal products and minerals. From his explorations he developed a variety of therapeutic agents. Over time, the effective agents amongst them were selected by a process of trial, error, empirical reasoning and even by experimentation. These efforts have gone in history by the discovery of "Medicine".

In many eastern cultures such as those in India, China and the Arab Persian world, this experience was systematically reported and incorporated into the regular system of Medicine which was refined and developed and which became a part of the Materia Medica of these countries. The Indian System of Medicine and Homeopathy (ISMH) consists of four major systems namely: AYUVERDA, UNANI, SIDDHA, HOMEOPATH.

In 1995 an independent department of ISM&H was set up in the Ministry of Health and Family Welfare.
The objectives of establishing such a department were;

1. To upgrade the educational standards in the ISM&H colleges in the country.
2. To strengthen existing research institutions and ensure a time-bound research programme on identified diseases for which the systems have an effective treatment.
3. To draw up schemes for promotion, cultivation and regeneration of medicinal plants used in these systems.

4. To evolve pharmacopoeia standards for ISM&H drugs.

They also have:

- Indian legislation to regulate Ayurvedic Medicine
    * Indian Medicine Central Council Act (1970) on education & registration
    * Drugs & Cosmetic Act (1940) & rules made thereunder
    * Magic Remedies (objectionable advertisement) Act
- Statutory bodies
    * Ayurveda, Siddha, Unani Drugs Technical Advisory Board
    * Drugs Consultative Committee

-Ayurvedic Pharmacopeia of India

-Ayurvedic Formulatories of India

It has been noted that many plants available in Abuja are used in Ayurveda sometime for similar functions.

PAPER 5

PRESENT TRENDS IN MEDICINAL AND AROMATIC PLANTS RESEARCH:
AN AFRICAN PERSPECTIVE (Dr. Ermias Dagne, Ethiopia)

Chemical studies not only contribute to advancing knowledge but also help in finding ways and means of adding value to natural products in the country of origin.
At present, much effort is directed by the scientific community from Africa and elsewhere towards the study of the botany, chemistry and pharmacology of African plants. Therefore considerable amount of information is now available in literature. It is important to draw lessons which are relevant to the establishment of the medicinal plant industry. The case of the actual industrial exploitation of an African plant, *Aloe Vera*, outside Africa is presented. Also presented is the big potential existing in the utilisation of essential oils for the treatment or prevention of some diseases. Thus African countries should take measures to protect their traditional knowledge so that repective communities would benefit from this heritage. A data-base is prepared on results of phytochemical studies on plants originating from Africa. This appeared in leading natural products journals. Typically, most of the chemistry-oriented papers report isolation and characterisation of novel compounds from the African Flora. It has been mentioned that the protection of Intellectual Property Right is at quite a low level when compared to what obtains in developed countries.

In conclusion, effort should be intensified to increase the awareness of modern physicians of the value of alternative medicine. Therefore, alternative medicine should be part of the curricula of medical schools.

PAPER 6

OWNERSHIP AND SUSTAINABILITY ISSUES OF HERBAL MEDICINES
(Prof. Gamaniel K. Shingu, Nigeria)

There is a growing recognition that biological diversity including medicinal plants is a global asset of tremendous value to present and future generations. The principal objectives of the Convention of Biodiversity (CBD) are the conservation and sustainable use of biological diversity and the fair and equitable sharing from its

utilisation. Despite the good progress made since the signature of the declaration of Biodiversity (CBD) in June 1992 at Rio de Janeiro, the mechanism by which this will be realised is not yet in place. There is a great need for it to be spelt out as soon as possible. There is a need for toal re-orientation on the current practice of herbal medicine. Practitioners must be aware of how plants contribute to life. A sustainable use system should be evolved which will guarantee that the local people realise benefits from these medicinal plant resources in such a way that they will be encouraged to contribute to their conservation.

PAPER 7

PROCESS TECHNOLOGY FOR THE EXTRACTION OF MEDICINAL/AROMATIC PLANTS ON A PILOT SCALE (Engr. Elias N. Amlabu, Nigeria)

Studies carried out on multipurpose pilot plant used for extraction of both medicinal and aromatic plants have been a source of technological info-data bank meant for prospective scale up to the industrial level.
Essential oils were extracted from the following plants: *Eucalyptus citriodora, Eucalyptus camadulensis, Cympobogon citratus* (lemon grass), *Zingiber officinale* (Ginger) *and Lippia multiflora.* Their yields were encouraging and comparable to the records of existing literature for Ginger.

Similarly, extracts obtained from medicinal plants are being formulated into drugs for the management of Sickle Cell anamia (NIPRISAN), Skin fungi attack (AF1) and AIDS (NIPRID-HIV). These essential oils and medicinal plant extracts are still undergoing laboratory microbial activity test and quality control test.

PAPER 8

BIO-GUIDED EXTRACTION/ISOLATION OF A MEDICINAL PLANT (Dr. Nkechi M. Enwerem, Nigeria)

Plants are sources of drugs. The selection of a plant specie for scientific investigation is the most crucial factor in research on medicinal plants. There are different ways of selecting a plant. This can be through random collection, literature or exploitation of ethnomedical information. The process of transforming a plant to a pharmacologically active, pure constituent is long and expensive. It involves a series of consecutive steps. The first step is the screening of the crude extracts of the medicinal plant in a bio-guided approach. This should be simple, rapid, reproducible, inexpensive and able to accommodate the screening of a large number of compounds. Bioassays can be carried out on lower animals (micro-organisms, insects, molluscs), cultured cells of human or animal origin, isolated organs of vertebrates or whole animals.

PAPER 9

STANDARDIZATION OF HERBAL MEDICINES

(Dr. Obiageri Obodozie, Nigeria)

An objective scientific evaluation of herbal medicines will enhance the incorporation of proven herbal products and practices into the public health care delivery system.

For herbal medicines to be integrated or incorporated into the public health care delivery system, adequate scientific evaluation consisting of chemical and biological analyses using modern technology has to be put in place. In addition, a registered herbal medicine should have comprehensive information about its scientific analysis, therapeutic validity, toxicity, the right dosage and attendant side effect(s), if any.

The standardization of herbal medicines is done at different stages of herbal production namely chemical, microbiological, pharmacological, toxicological and pharmaceutical.

PAPER 10

COMMERCIAL PRODUCTION OF HERBAL MEDICINES

(Dr. Mariane Ngoulla, WHO/AFRO, Zimbabwe)

WHO/AFRO has developed a Regional Strategy on promoting the role of traditional medicines in the health care systems. This strategy will be presented during the Regional Committee 50 in Ouagadougou at the end of August 2000. One of the five-priority area is developing research for large scale production of traditional medicines including cultivation and biodiversity conservation.

In this regard, five diseases have been selected as priority diseases: Malaria, HIV/AIDS, Hypertension, Diabetes and Sickle cell anaemia. To make traditional medicines available in the health care systems, the Regional office for Africa is developing a legal framework to organise, regulate, develop a large scale production of traditional medicines and to ensure their rational use, the protection of intellectual property right and the cultivation and conservation of MAPs. The evaluation of the safety, efficacy and quality of traditional medicines is a key point which should be based on documentation validation (using the available data in different parts of the world) and clinical evaluation according to the code of ethics. The clinical evaluation should take into account the available information on ethnomedical evidence.

Some phytomedicines are already registered and patented in some countries. For example NIPRISAN for Sickle-cell anaemia in Nigeria, Madeglucy1 for diabetes in Madagascar, Mistmora for Malaria in Ghana, Mistcedenia for mild hypertension in Madagascar and Dopravil for HIV/AIDS in Nigeria.

PAPER 11

CLINICAL TRIALS OF HERBAL MEDICINES: CHALLENGES AND PROSPECTS

(Prof. Charles Wambebe, Nigeria)

WHO described clinical trials as follows:
"A systematic study on pharmaceutical products in human subjects (including patients and other volunteers) in order to discover or verify the effects of and/or identify any adverse reaction to investigational products, and/or to study the absorption, distribution, metabolism and excretion of the products with a view to ascertaining their efficacy and safety". Clinical trials are generally classified into phases I to IV.

Since herbal medicines have a long history of usage in some cases spanning over a thousand years, with oral or written evidence of efficacy and safety, some people deem it a wasteful process to conduct controlled clinical trials of herbal medicines.

In Africa generally, the substantial resources required for conducting a good clinical trial are not readily available. The possible undesirable interactions between herbal and orthodox medicines may pose a serious problem since most patients may, on their own, take both orthodox and herbal medicines concurrently even when advised against such a practice. The qualitative and quantitative variations associated with plant constituents due to seasonal changes create an important problem with regards to standardisation. Good laboratory practice (GLP) is not yet imbibed by most scientists in Africa.

In fact, the psychological block against conducting a good clinical trial using herbal medicines may scare away some people from attempting to conduct such studies. These problems can be regarded as challenges which can be overcome if we are serious and determined. As part of the need to protect the trial subjects from known and unknown risks involved in such studies, the provision of the declaration of Helsinki should be followed strictly.

In the past six years, National Institute for Pharmaceutical Research and Development (NIPRD) has been involved in the development and preparation of clinical protocols for the efficacy and safety of herbal medicines. To date, developed six protocols which are now being used for Phases II and III clinical trials of some of the medicines developed by NIPRD. One of such products, NIPRISAN is undergoing Phase III multicentre placebo controlled randomized cross over clinical trial. NIPRISAN is a herbal product developed by NIPRD in collaboration with Rev. Ogunyale who gave NIPRD the initial recipe for the prophylactic treatment of Sickle Cell Anaemia. The on-going clinical studies will be conducted within the next nine months. Thereafter the new product will be registered, prescribed and included in the national essential drug list. The research and development of NIPRISAN was essentially funded by UNDP. UNDP also paid for the patenting of NIPRISAN in 46 countries in Africa, Asia, Europe and America. Other products developed in NIPRD at different stages are NIFADIN, for the prophylactic treatment of Sickle Cell Anaemia (Phase II clinical trial has been conducted). NIFRIPAN, for the treatment of anti-fungal infection (clinical trial has been conducted for the past four years) two drugs Deprovile and Conival, have been developed to combat HIV/AIDS (Phase II of their clinical trials will start next month; an anti-malaria agent (WHO has promised to fund the clinical trial); an oral contraceptive has been developed in collaboration with the University of Jos. Its clinical trial will start after the approval of the NIPRD Ethical

Committee. For the past four years, over 500 women have used this oral contraceptive which is effective for six months after a single oral dose. This preparation will be ideal for most women, especially those in the rural areas. WHO/AFRO has openly challenged us to submit appropriate data which may justify the mass production of any proven herbal medicine in Africa. We must positively do all we can to respond to this challenge.

PAPER 12

IMPROVING PLANT MEDICINE FOR HEALTH CARE DELIVERY IN GHANA (Dr. Alexander K. Nyarko, Ghana)

Plant medicine is patronized by majority of Ghanaians, both literate and illiterate, especially the rural folk who do not have easy access to modern health care facilities. The practice is based on societal beliefs some of which are at variance with Science. However, Science can be harnessed to produce effective, safe and quality plant medicines that are universally acceptable. In view of this, the government of Ghana has enacted laws to facilitate the development of plant medicines with the ultimate goal of its future incorporation into the official health care delivery system. The enforcement of government regulations, the application of Science and the upholding of proper code of ethics could uplift the practice and quality of plant medicine to meet professional and client expectations. Also it would ultimately facilitate its universal acceptance and incorporation into the national health care delivery system.

For effective regulation, the practitioners need to be organized into a body. The six independent associations of traditional medicine in Ghana have formed The Ghana Federation of Traditional Medicine Association (GHAFTRAM). It is the body currently recongnized by the government.

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Universities and research institutes in Ghana are actively pursuing research on several aspects of plant medicine. One institute, the Center for Scientific Research into Plant Medicine (CSRPM), a collaborative center on Traditional Medicine which was established in 1975, is specially charged to conduct and promote scientific research relating to the improvement of plant medicine and establish, where necessary, botanical gardens for medicinal plants.

PAPER 13

APPROACHES PURSUED IN SOUTH AFRICA TO STRENGTHEN THE UTILISATION OF MEDICINAL PLANTS AND TRADITIONAL MEDICINE IN THE HEALTH CARE SYSTEM (Mr. Isaac Mayeng, South Africa)

Efforts pursued to strengthen the utilisation of medicinal plants and traditional medicine in the national health care system in South Africa occur at government and non-government levels (Health Product Associations, Traditional Medical Practitioners Associations and Consumers Trade Unions)

The Department of Health, National Drug Policy for South Africa stipulates investigation of the use of effective and safe traditional medicines at primary level. It calls for the investigation of traditional medicines for efficacy, safety and quality with the aim of incorporating their use in the health care system; the registration and control of marketed traditional medicines; and the establishment of a National Reference Centre for African Traditional Medicines (NRCATM)

The establishment of NRCATM has been approved by the National Minister of Health. The functions of the center will be developing a national database; testing of toxicity and efficacy; compiling a national formula for medicine-control; granting approval for essential traditional medicines; propagating of medicinal plants. The regulatory framework for registering traditional medicines is done under the Medicines and Related Substances Control Act (1965). A special expert committee of the Medicines Control Council named "African Traditional Medicines Committee" is being established. As a mechanism for collaboration between health care providers and other stakeholders, members of trade unions are pressurizing their employers to accept sick leave certificates issued by traditional medical practitioners. They are also pressurizing the medical aid scheme to cater for the services provided by traditional medical practitioners.

PAPER 14

THE INTEGRATION OF TRADITIONAL AND MODERN MEDICINE IN THE UTILISATION OF MAPs IN THE NATIONAL HEALTH CARE SYSTEM (Dr. Paulo P. Mhame, Tanzania)

The practice of traditional medicine in Tanzania is as old as humankind. Currently, it is estimated that there are about 75,000 traditional healers in Tanzania. This exemplifies a ratio of 1:320 compared to the conventional doctor/patient ratio of 1:20,000

In order to have a better management of the development, use and conservation of the enormous wealth in medicinal resources, modern African scientists should find all possible modalities for integrating the two systems. African scientists should follow the examples of other countries like China which has developed and integrated its traditional medicine practice through research.

There are various "models" for developing and integrating traditional medicine into the national health care system. Successful nations have found that only the traditional model proved successful in researching, promoting and integrating traditional medicine into national health care systems.

The traditional model method has five stages:

1. The traditional health practitioner and the community
2. Verification centers (Clinical research centers)
3. Research Institute
4. Pharmaceutical factory
5. Users.

Traditional health practice is here to stay, whether or not efforts are geared towards its promotion. There is no longer any doubt about the value of incorporating traditional medicine into modern health care. Many reasons are accountable for this. However, the basic reason is that people believe that traditional medicine practices have values to which they are willing to subscribe.

PAPER 15

PROMOTING THE USE OF TRADITIONAL HERBAL MEDICINE IN THE NIGERIAN HEALTH CARE SYSTEM (Dr. Tolu Fakeye, Nigeria)

Traditional Herbal Medicines (THM) enjoys wide popularity in Nigeria because it is simple, culturally acceptable and holistic. Also traditional medicine practitioners are available at the grassroots. To promote the use of traditional medicinal plants, some strategies are developed taking in account the fact that TM should be conceptualized beyond medicine/drugs. This is because TM is a body of knowledge and practices which evolved from customs and traditions. Therefore, there is a mystic unity between the practice and the practitioners. Some policy-related strategies are developed for the regulation of traditional medical practitioners in the health-care system and also for traditional medical products. In this regard, the national traditional medicine development programme established in 1997 constituted a National Technical Working Group on TM. So far a policy document has been articulated which contains a code of ethics, draft decree for Federal Traditional Medicine Board and a draft edict for state boards on TM. Minimum standards for TM Practice in Nigeria has also been established. In addition a curricula on TM has been developed which include a diploma course in Traditional Herbal Medicine; Herbal Medicine Ingredient Selling; Traditional Bone Setting; Traditional Mental Health and Traditional Birth Attendance.

PAPER 16

EXPECTATION OF THE INDUSTRY (Dr. Femi Rabiu, Nigeria)

The Pharmaceutical Manufacturers Group of Nigeria (PMG-MAN) is a member of the executive committee of NIPRD. The group has expressed a big interest in the work done by NIPRD. The following are some of its expectations:

*More information on projects: Stages of development; Issues of standardization/toxicity; Issues on availability, sustainability and preservation; Required technology/scale of activities; Investment profile.

*Concerted efforts towards the re-orientation of citizens: Government health policy to stimulate the market.

*Issues of intellectual property, rights and patents: To assure returns on investment.
*Encouragement of inter-country/continent collaboration. The Indian experience.

Institutions/Research organizations/Multilateral organizations e.g. WHO should develop a plan of action to address these expectations. The pharmaceutical industry is ready to develop aggressive and visible collaboration with research units as a strategy for future business enterprise.

PMG-MAN will continue to support these efforts through drafting of policy guidelines for government.

- -A 3-tier or multilateral funding pattern is recommended for agriculture-the establishment of land or large-scale herbarium;
- -Pharmaceutical manufacturers for investment in the production of herbal medicines

-relevant expertise to support programmes such as feasibility studies.

ANNEX A

REGISTRATION FORM

[Print in Capital Letters]

Title: Prof./Dr./Mr/Mrs/Ms/:.....

Other Name(s) :.....

[Underline Surname]

Institution:.....

.....

Postal Address:.....

Post Code:..... City:.....

Country:..... Tel:.....

Fax:..... Email:.....

ANNEX B

INTRODUCTION OF ICS BY SCIENTIFIC CONSULTANT, EARTH, ENVIRONMENTAL AND MARINE SCIENCE AND TECHNOLOGIES (ICS-UNIDO)

PRESENTED IN

INTERNATIONAL WORKSHOP ON
"STRATEGIES TO STRENGTHEN THE UTILISATION OF MEDICINAL AND AROMATIC PLANTS IN THE NATIONAL HEALTH CARE SYSTEM"

ABUJA, NIGERIA (11 - 13 JULY 2000)

BY

DR. KARAN VASISHT
ICS-UNIDO
99, PADRICIANO,
AREA SCIENCE PARK
TRIESTE
ITALY

Industrial utilization of medicinal and aromatic plants

Promoting sustainable growth of industry based on medicinal plants in developing countries

Providing support through training courses, fellowships, workshops, publishing manuals and creating a network of databases

Creating a network of leading institutes from different countries for technical cooperation

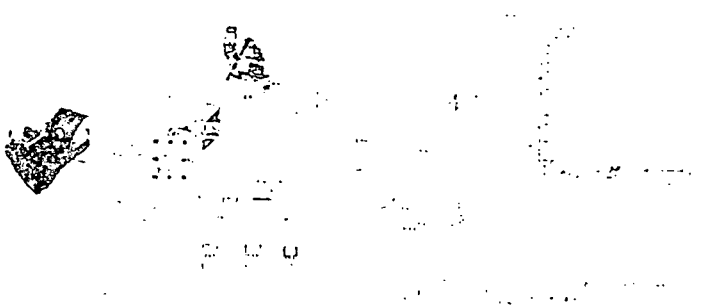
Developing and working on demand based projects

UNIDO International Centre for Science and High Technology

Technologies for sustainable industrial development

- Reinforce decision-making process for sustainable industrial development

- Exploit modern technical tools:
  - Process simulation
  - Remote sensing
  - GIS
  - Image processing



UNIDO International Centre for Science and High Technology

Steering Committee

- Italian Government representatives
- Representative of Developing Countries
- UNIDO representative

UNIDO International Centre for Science and High Technology

Cooperation with International Organizations

UNIDO

(United Nations Industrial Development Organization)

UNEP/MAP

(Mediterranean Action Plan)

MCSD

(Mediterranean Commission for Sustainable Development)

CEI

(Central European Initiative)

UNIDO International Centre for Science and High Technology

Training Activities
1988-1999

266 Workshops, courses, conferences

8754 Participants (including individual training & expert group meetings)

UNIDO International Centre for Science and High Technology

Environment subprogrammes

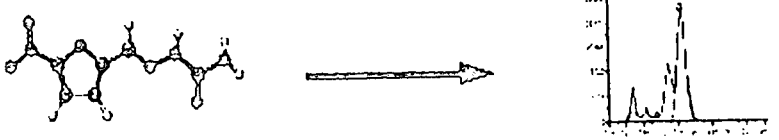
- **Technologies for sustainable industrial development**
- **Coastal Zone Management**
- **Industrial Utilization of Medicinal and Aromatic Plants**

Strategies to strengthen the utilization of MAPs in the national health care system

- *Document and prioritize list of important plants according to established use*
- *Public awareness*
- *Provide scientific basis*
- *Corroborate results, avoid duplication and share resources*
- *Standardization of traditional medicines*
- *Strengthen existing infrastructure*
- *Suppliers and manufacturers should fund validation projects*

UNIDO International Centre for Science and High Technology

Pure and Applied Chemistry

- Catalysis and sustainable chemistry
- Biodegradable plastics 
- Remediation
- Combinatorial Chemistry and Technologies

National Summit for US policy plan for Africa in 21st Century

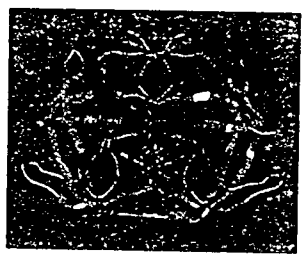
- *US to encourage support for traditional medicine sector*
- *Review to upgrade and improve use of trad medicines*
- *Prohibit pharma companies to exploit traditional knowledge without due compensation*
- *To explore, encourage and improve the rational use of low-tech traditonal medicines*
- *NGO's and GO's to create and support education and use of traditional medicines*
- *US to encourage and support R&D to produce safe, stable and natural healthcare products*

National Summit on Africa for National Policy Plan of Action
Washington , 16-20 Feb 2000

UNIDO

International Centre for Science and High Technology

Fields of Activity



Pure and Applied Chemistry

Earth, Environmental and Marine Sciences and Technologies

High Technology and New Materials

UNIDO ICS International Centre for Science and High Technology

Objectives of ICS

- to foster and facilitate the transfer of technology in specific high-tech areas to developing countries

- to provide high-tech SMEs in developing and transition-economy countries with advanced tools and services for the enhancement of their sustainability and competitiveness

UNIDO International Centre for Science and High Technology

Coastal Zone Management

- Sustainable development of coastal economics
- Integration of scientific, economic, legislative aspects
- Application of decision support systems for:

  - industrial siting
  - resource management and control
  - control and monitoring of pollution
  - marine navigation control

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Project proposals

- traditional training activities at ICS support the identification and formulation of projects, which are submitted to donors for funding

- project proposals are identified and implemented with the support of experts and fellows from industries or institutions

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High technology and New Materials

- ***high technology***

  laser applications and optical technologies for industry and medicine

- ***new materials***

  composite materials for low-cost housing

- ***photovoltaic solar energy***

  diffusion of pv systems and applications

- ***telecommunication technologies***

  radio communications, fixed, mobile, satellite and rural networks

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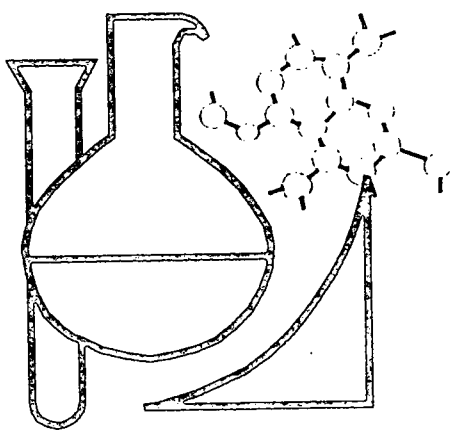
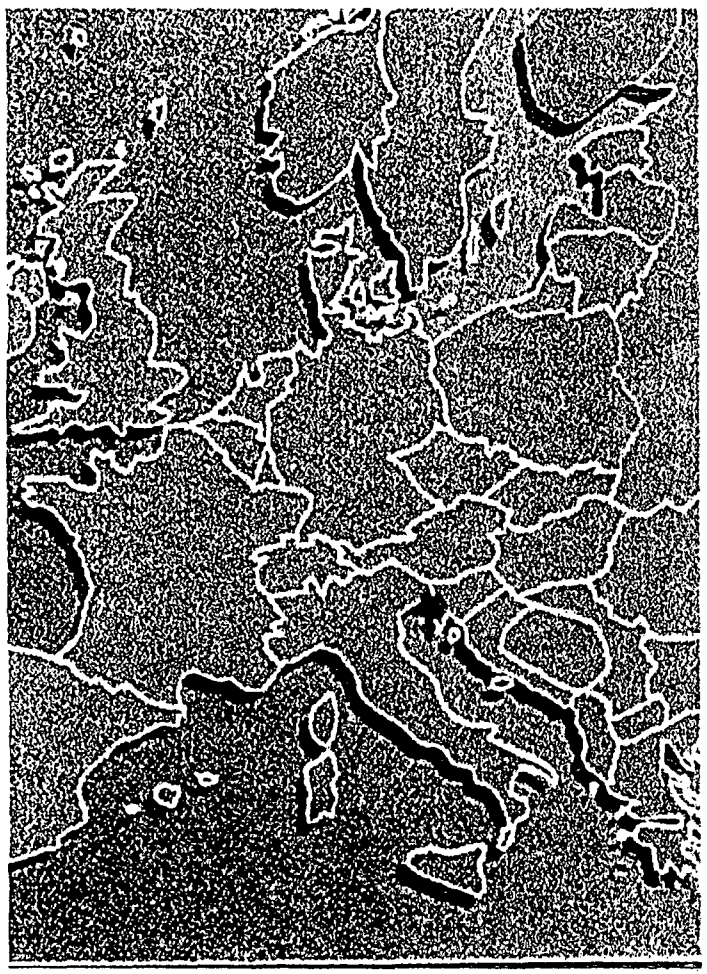
Pure and Applied Chemistry

- innovation of processes directed at the prevention of pollution

- development of cleaning processes



ICS-UNIDO - Trieste, ITALY



ICS is headquartered at the AREA Science Park, close to the city of Trieste. The AREA is home to many organizations.

ICS works with the main institutions in Trieste and has special collaborations with the UN centres

Strategies to strengthen the utilization of MAPs in the national health care system

Immediate, conclusive and concerted efforts are required to promote use of traditional medicines and also to safeguard and conserve medicinal species for the future generations

UNIDO ICS International Centre for Science and High Technology

Karan Vasisht

Scientific Adviser

Industrial Utilization of Medicinal and Aromatic plants

Earth, Environmental and Marine Sciences Area

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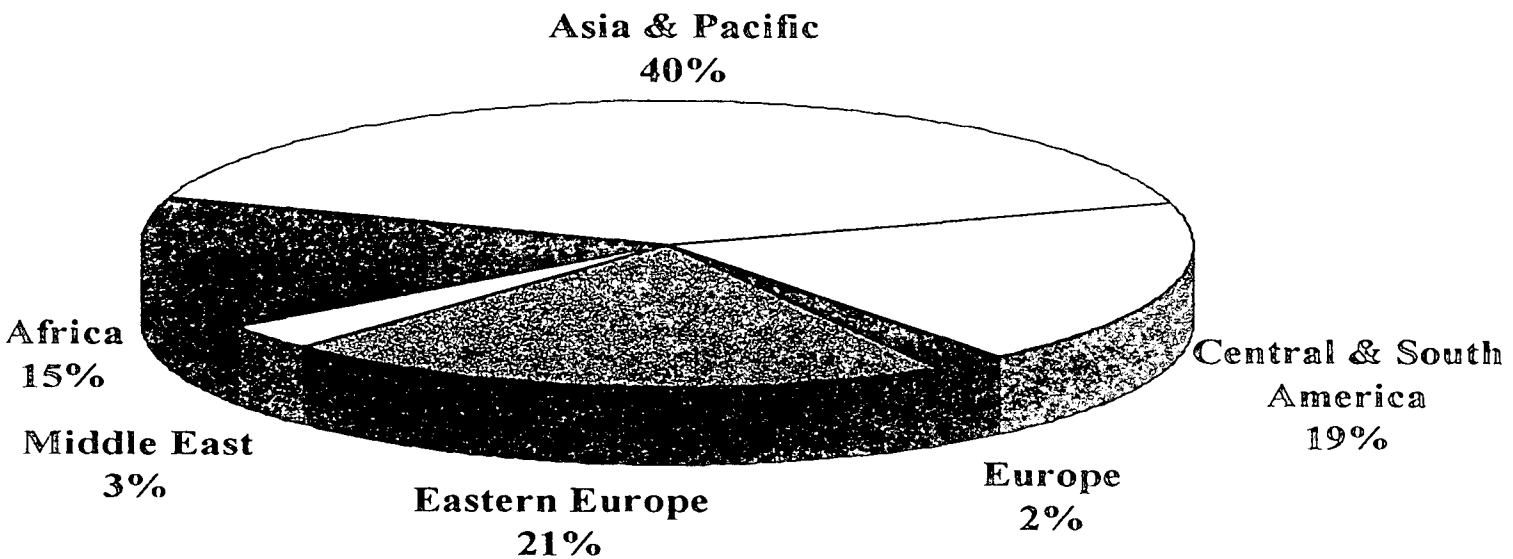
UNIDO

International Centre
for Science and High Technology

Training for Developing Countries



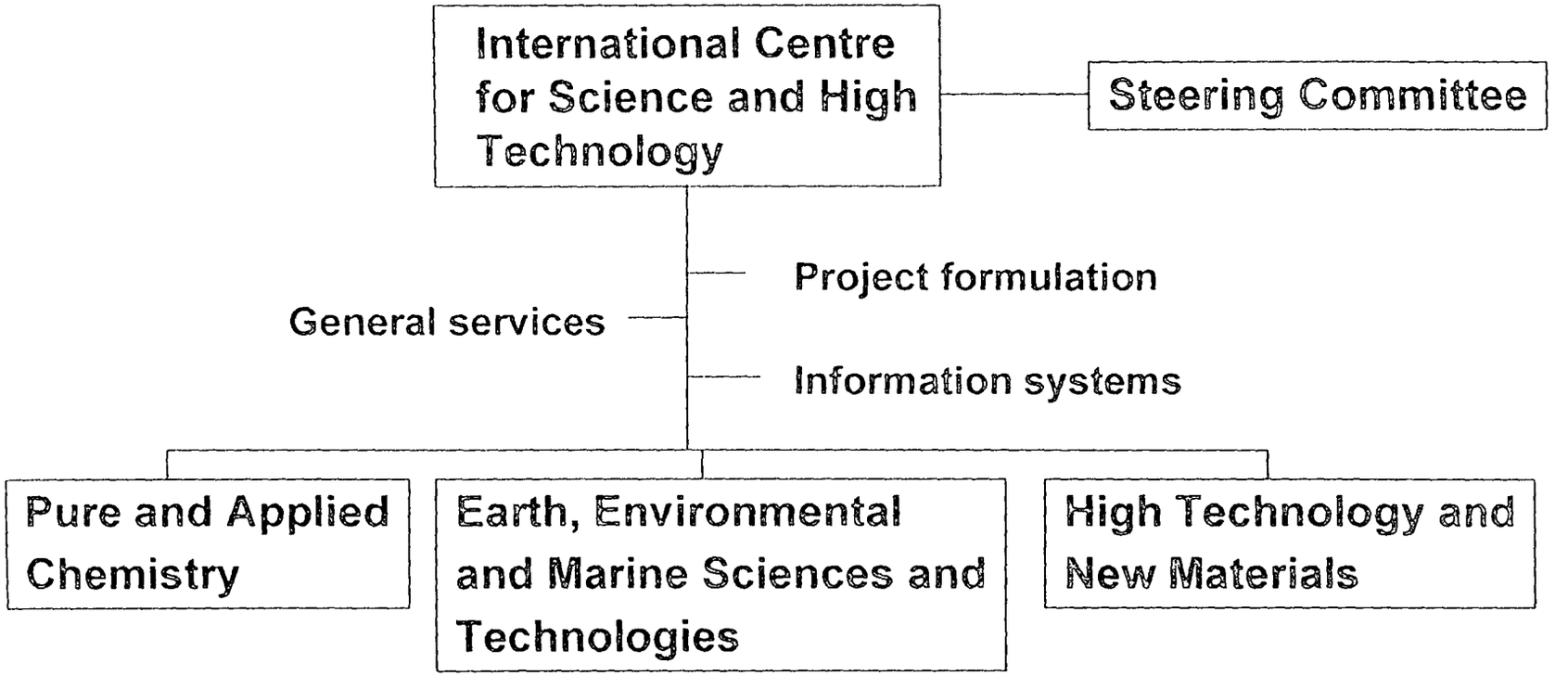
UNIDO ICS International Centre for Science and High Technology

ICS

Autonomous Institution operating within UNIDO legal framework

UNIDO International Centre for Science and High Technology

Institutional Structure



UNIDO (C) International Centre for Science and High Technology

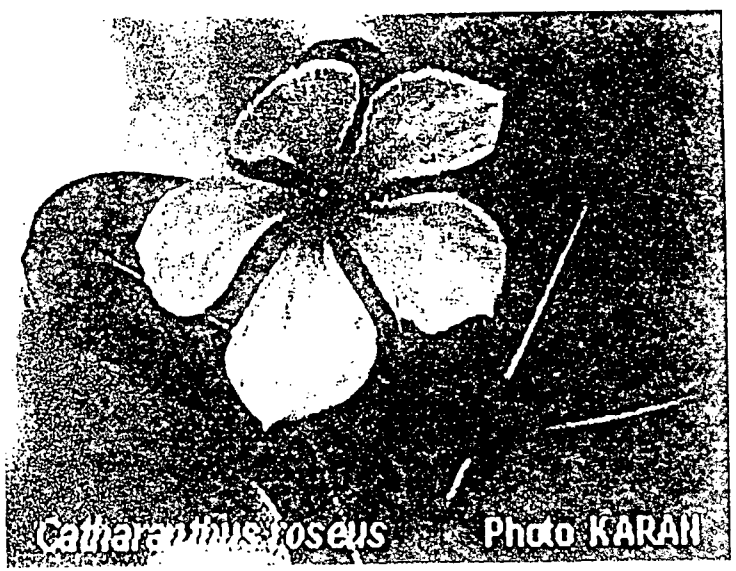
Earth, Environmental and Marine Sciences and Technologies

- impact analysis of industrial development
- sustainable industrial exploitation of natural resources
- forecasting and monitoring
- process simulation

for Science and High Technology

Industrial Utilization of Medicinal and Aromatic Plants

- Consolidation of existing technology for developing countries
- Technical assistance in product R&D
- Raising government awareness



UNIDO ICS International Centre for Science and High Technology

General Framework

- training courses
- scientific workshops
- high-level seminars
- fellowships
- publications and training packages

ICS target beneficiaries and counterparts

- National/regional R&D institutions
- National policy and strategy decision-makers
- High-tech SMEs

UNIDO ICS International Centre for Science and High Technology

Networking

Identification in various regions of the world, selection and evaluation of partner institutions willing to offer

co-operation and support

UNIDO

International Centre
for Science and High Technology

Founded by

Nobel prize-winner Professor Abdus Salam in 1988

Supported by Italian Government

Headquarters: Trieste, Italy

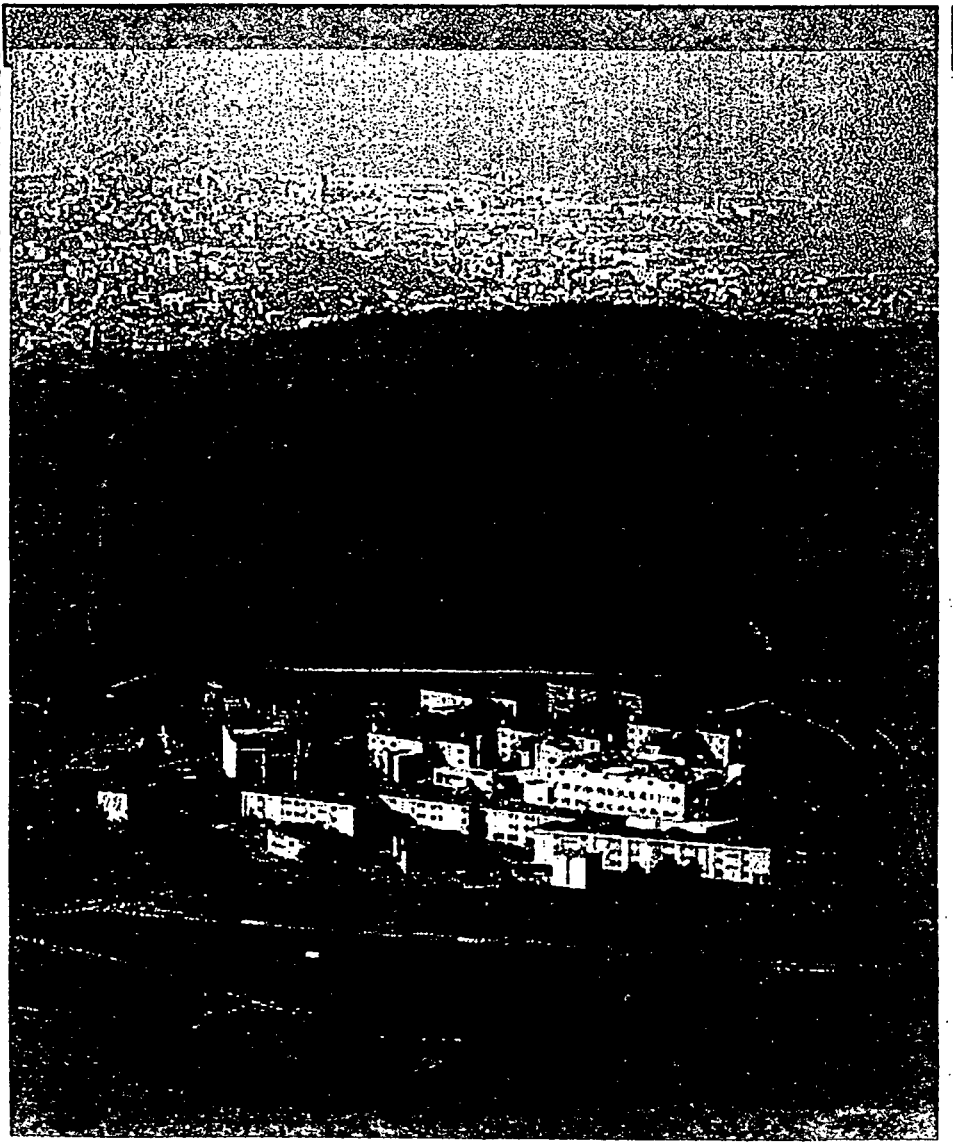
(within the Area Science Park)

Strategies to strengthen the utilization of MAPs in the national health care system

- *Increasing cost of modern medicines*
- *Inaccessibility and cost of prescription*
- *Acceptance of trad medicines and their emphasis on holistic approach*

- *Scattered & undocumented information*
- *Element of secrecy*
- *Lack of mutual respect and harmonization*
- *Lack of standardization*

Contacting ICS



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ANNEX C

AN ADDRESS BY MRS PAULINE K. TALLEN THE HONOURABLE MINISTER OF STATE; FEDERAL MINISTRY OF SCIENCE AND TECHNOLOGY AT THE INTERNATIONAL WORKSHOP ON "STRATEGIES TO STRENGTHEN THE UTILIZATION OF MAPs IN THE NATIONAL HEALTH CARE SYSTEM" ON TUESDAY 11TH JULY 2000, 10 am AT PILOT PLANT FACILITY NIPRD, IDU.

PROTOCOL

It is my pleasure to be here this morning to participate in the opening ceremony of the workshop on "Strategies to Strengthen the Utilization of Medicinal and Aromatic Plants (MAPs) in the National Health Care System". I understand that the Workshop has been put together by ICS-UNIDO IN COLLABORATION WITH THE National Institute for Pharmaceutical Research and Development (NIPRD).

On behalf of the Government and people of Nigeria we welcome our foreign participants to this workshop. We also welcome other dignitaries that have found time to grace this occasion.

In 1978 the World Health Organisation (WHO) urged the use of Primary Health Care as the core strategy for achieving health for all by the year 2000. It is obvious that we are still very far from the target. In 1993 the Scientific, Technical, and Research Commission of the Organisation of African Unity (OAU) organized a symposium on African Traditional Medicine and Medicinal Plants. The programme of the meeting included eight (8) themes on the promotion of traditional medicine, the use of traditional medication in primary health care, research and development of drugs derived from medicinal plants, plant bio-diversity, the tropical environment, clinical tests and inter-African and international co-operation.

An important fall-out of that symposium was the extra-ordinary dimension taken by extensive research, and the interest aroused in favour of African traditional medicine and medicinal plants.

The recommendations of that workshop urged member states

1.To develop mechanisms geared towards a sustainable exploitation of their Bio-genetic reserves.

medical practitioners and medical researchers.

3. To study the possibility of establishing legal instruments to protect Traditional Medical Practitioners and the population from mal-practices of quacks.

4. To introduce some aspects of traditional medicine and the study of African medicinal plants in the curricular of Schools of Medicine and Pharmacy.

5. To develop a research programme on AIDS that closely involves Traditional Medical Practitioners.

These recommendations are as valid today as they were at the time they were made. None of us is unaware of the inherent potential and immense contributions of traditional medicine to our public health. For thousands of years people in many cultures have treated their sickness with herbal remedies using plants from our fields and forests. The reasons for this is not difficult to discern. The most readily accessible and cheap health care facilities are those traditional medicine which have been found to be effective particularly in the treatment of ailments where orthodox medicine has provided no ready solution.

This realization had led to an unprecedented revival of public, as well as scientific interest in herbal teas, herbal medicines and other herbal products. Consequently there has been phenomenal growth of the herbal medicinal products, essential oils and extracts in recent years. Increasing number of people are seeking natural health care alternatives and many orthodox physicians are showing increasing interest in and use of herbal therapy. Traditional Medicines are receiving greater attention of international health bodies in an effort to confront the high cost of modern drugs to achieve health for all.

It is this renewed interest in the therapeutic value of herbal medicines that makes this workshop very relevant. The discovery and development of a new drug molecule has almost become the exclusive preserve of the developed world. The high cost of such enterprise forbids the entry of most developing countries into this arena. The expected financial return is an important driving force in defining research direction of pharmaceutical firms in the developed world. The poor nations are therefore left at their mercy for specific health problems in their countries. However, strengthening the use of traditional medicines by providing scientific basis is well within the ambit of developing countries.

It is therefore important that developing countries should look inwards and device strategies within their economic competence to meet their health care needs.

I am informed that the workshop will address the following topics:

1. Scope and role of traditional medicine in health care systems of developing.

2. Challenges, constraints and opportunities in traditional medicines in the African continent.

3. The successful example from different countries

4. The present trends in medicinal plants research, Future research needs and challenges of developing nations.

5. Ethno-pharmacological investigations and production of drugs from medicinal plants

Topics related to documentation, validation and safety evaluation of traditional medicines production of standardized herbal drugs, issues of bio-diversity conservation and production opportunities of medicinally important plants, medicinal plants in African continent, will also be discussed during the workshop.

I am glad to note that all of you attending this workshop today are experts from the drug industry, research Institute and bodies involved in research and development of drugs from medicinal plants. Experts working in traditional medicines and designing of health policies are also present. Although the workshop would focus more on the African continent, experts from other developing and developed countries are here to enrich the discussions and the presentations in this workshop.
We welcome you all.

Ladies And Gentlemen, the successful application of Science and Technology to strengthen the use of herbal medicine in Nigeria, is not something unattainable. Successes in this area in other countries give grounds for optimism about its prospects in our socio-economic development.

The success stories of China and India can be analysed as role models. These countries which had strong system of traditional medicines also had the advantage of well-documented information. They have successfully integrated the alternative system with modern medicines to the extent that traditional Chinese medicine hospitals are as adequately staffed and well equipped as Western medicine hospitals, featuring modern diagnostic and treatment equipment with appropriate computer attachments.

It is to underscore the seriousness of the Federal Government in this integration process that the National Institute for Pharmaceutical Research and Development (NIPRD) was established in 1989. One of the Institutes primary mandates is to develop methodologies for quality assessment of both orthodox and herbal medicines in Nigeria, including their raw materials. Prior to the establishment of the National Institute for Pharmaceutical Research and Development (NIPRD) there had been a Drug Research Unit at Obafemi Awolowo University (OAU) Ife, and medicinal plant research activities in other Nigerian Universities, particularly those at Nsukka, Benin and ABU Zaria. This workshop for which we are here gathered today is therefore one giant step forward in buttressing the role of scientific research and development as a bridge upon which the successful integration of herbal medicines in our National Health Care System hinges.

Eminent Scientists, Honourable Guests, Ladies and Gentlemen, there are great challenges in the scientific research and development of African traditional medicine. They include not only the substantial financial investment that must be made in men and equipment, but also the need to find ways of working together among inter disciplinary teams of African Scientists and traditional and Western practitioners, as well as with scientists and practitioners, from other lands - for the purpose of transforming African herbal drugs and traditional remedies into modern medicines.

I commend the organizers of this workshop, and the focus, which is in tune with the thinking of the present administration in its health care delivery efforts. It is my belief that useful recommendations would emanate from the workshop that would be helpful to Government in charting an improved course of action for the country in this direction.
I wish you all a very fruitful deliberation. And to our foreign participants, I suggest you find time to look around and enjoy our hospitality. At the end of the exercise, I wish you safe journey back to your respective countries.
It is now my unique privilege to declare the Workshop open.

Thank you and God Bless.

MRS PAULINE K. TALLEN
HONOURABLE MINISTER OF STATE,
FED. MIN. OF SCIENCE AND TECH.,ABUJA.

ANNEX E

ICS-UNIDO/NIPRD Workshop on *"Strategies to Strengthen the Utilization of MAPs in the National Health Care System"*, 11-13 July 2000, Abuja, Nigeria

THE ROLE OF MEDICINAL AND AROMATIC PLANTS FOR HEALTH CARE NEEDS OF DEVELOPING COUNTRIES

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Introduction

Medicinal and aromatic plants have been used as a source of medicine as well as to enhance the quality of life since time immemorial in almost every country. The process of learning of the beneficial and harmful features of plants has taken many centuries and the accumulated knowledge have been continuously sieved and distilled. In the process, unworthy information was neglected and soon forgotten while the valuable and useful information was retained and passed on to next generations. In most countries the information was distributed verbally. In some ancient civilizations, however, it was recorded and the art and science of healing began when traditional systems of medicine reigned. In these countries where there is a traditional system of medicine, the principles and materials of the system have survived to date through its uninterrupted practice. Therefore, there is considerable certainty about the identity of the materia medica and processes to prepare medicines. Such systems exist in India and China where modern evaluation of the systems is providing us with new leads for developing medicines to combat common diseases of our day.

Traditional systems of medicine have not only provided us with a system to diagnose illnesses and remedies but also combined plant, animal and mineral drugs to prepare compound medicines. Most of these time tested formulas are officially recognised and manufactured in some countries like Japan. In Japan 147 Kampo medicines, meaning traditional Chinese medicines used in Japan for the last 1000 years, became eligible for reimbursement by the National Insurance Scheme in 1976. Based on the assumption that their safety and efficacy have been established through their centuries long use no clinical validation was thought necessary for these medicines to attain prescription status. As each Kampo formula has been given a number by the authorities, they can be manufactured by their numbers only. If indications are to be cited and a generic name is to be given, then, normal registration procedure for ethical medicines apply and clinical trials become a necessity [Başer].

In countries where verbal information has played a role in acquiring ancient knowledge, distortion and loss might have occurred rendering the validity of the information questionable. Uncertainty in identifying the origin of the plant material mentioned in old texts or verbal information puts, at times, the validity of the information in jeopardy. Therefore, ethnobotanical surveys are essential to regain and to validate the inherited knowledge.

World Pharmaceutical Industry

A WHO study in early 1980s had shown that 80% of the population of the world use herbal medication for their basic health care needs. This is due to the fact that developing countries manufacture only about 20% of the world pharmaceutical products. Therefore, people in developing countries do not have ready access to modern pharmaceuticals. 60

Countries in the world manufacture pharmaceuticals. Generic products are rather common in developing countries and pharmaceutical active ingredients are produced chiefly in developed countries. Only a few developing countries such as Argentina, Brazil, China, Egypt, India, Mexico, Korea, Porto Rico and Turkey produce pharmaceutical active ingredients [Uzuner].

In 1997, the total output value of the world pharmaceutical industry was USD 294 billion with USA, Europe and Japan being responsible for over 80% of the world production. These figures seem to indicate that the situation in developing countries has not improved but worsened in the last decade since, according to 1990 figures, 25% of the world population in developed countries had consumed 72% of the modern pharmaceuticals and 75% of the world population living in developing countries had to consume 28% of the global pharmaceutical production [Başer].

A recent estimate for the average cost of a successful new drug application in USA is USD 359 million over a period of 20 years. The cost of developing a herbal medicine in Germany in early 1990 was estimated as at least DM 50 million. Such high costs cannot be met by any company unless there is a reasonable expectation that a profit will be gained after the drug is marketed [Foster & Tyler].

In pharmaceutical industry, significant research and development investments are only made by multinational companies. Majority of the R&D investments are made by USA, Japan, Germany, France, UK, Switzerland, Italy and Sweden. In 1997, EUR 12 billion was spent on R&D in the EU. In the same year, the following number of new chemicals or bioengineering products came out: USA (20), Europe (19), Japan (7), Others (1) [Uzuner].

Such a high investment for R&D in pharmaceutical industry is not at all possible for developing countries. Therefore, they need to devise new ways of developing their own cost-effective medicines preferably from plants.

World Phytopharmaceuticals Industry

In 1999, the world wide sale of phytopharmaceuticals reached USD 19.6 billion. Compared with the USD 12.4 billion in 1994. This amounts to USD 7.4 billion increase in five years. Europe leads the market with an impressive sales volume of USD 7 billion. Europe is followed by Asia (USD 5.1 billion), North America (USD 3.8 billion), Japan (USD 2.2 billion) in retail price. Latin America follows with USD 600 million, Eastern Europe with about USD 400 million. The share of Africa + the Middle East, and the rest of the world is about USD 200 million each (Annex 1) [Grünwald 2000].

Within Europe, Germany holds the biggest share with USD 3 billion, followed by France with USD 1.8 billion, Italy with USD 0.8 billion, the UK with USD 0.7 billion, Spain and Scandinavia with 0.2 billion each and the Netherlands with USD 0.1 billion.

If we compare the sales figures of herbal remedies with those of 1994, the development of the North American market is obvious. In 1994, the total sales volume of phytopharmaceuticals there was only USD 1.5 billion. The increase in the last 5 years is more than two-fold [Grünwald 1996].

The expected growth rate of the phytopharmaceuticals market in the next two years is expected at around 8-10%. The marketing of herbal products has gained new strategies in recent years. Due to regularity constraints, the development of this sector was quite slow until 1994 in the USA. The same year, the Dietary Supplement Health and Education Act (DSHEA) became effective. This act defines herbs which have been shown to be useful in preventing chronic diseases as dietary supplements. They are considered as food and sold in dosage forms such as tablets, capsules, liquids, etc. They do not require a premarket approval

by the Food and Drug Administration (FDA). But no medical claims can be indicated. However, changes in the structure and function of the human body by phytomedicines can be mentioned in advertisements or product labels [Başer].

In April 1998, proposed rules for structure/function claims were published by FDA. These rules broadened the definition of disease and narrowed the limits of claims that a manufacturer can make on a product label. Dietary supplement labels with structure/function claims are required to carry a disclaimer stating: *This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease* [Foster & Tyler].

On January 6, 2000, the FDA issued its final regulations on structure/function claims for dietary supplements. The new rules represent a significant shift from those of April 1998. In the new rules, FDA has expanded the range of structure/function claims to include many conditions previously allowed for over-the-counter (OTC) drugs, such as antacid, antigas, anti-emetic, aphrodisiac, day-time sedative, digestive aid, laxative, night-time sleeping aid, stimulant, stool-softener, weight control [Anon. 2000; Israelsen & Blumenthal; Soller].

With the advent of this law, the dietary supplements market has boomed. In the USA, where dietary supplements have the largest share in the botanicals market with more than 80%. In Europe, however, they account for 15-20% of the herbal market. Regulations vary from country to country but the herbal remedies market is expanding in the developed world.

In Germany, an expert committee called "Commission E" which was established by the German Federal Health Agency reviewed the safety and efficacy of herbs in the German manrek and published the findings in the form of monographs in the German Official Gazette. By 1994, the Committee had issued 433 monographs of plant drugs and combinations with ca. 230 approved herbs. The monographs have, since then, been used to evaluate the marketing applications for herbal products. The monographs contain description of the product, its content, pharmacological properties, accepted indications, contra-indications, adverse effects, interactions with other drugs, dosage, quality requirements and recommended storage conditions. Positive Commission E monographs are widely used to document safety and efficacy of herbal medicines. Recently the Commission E monographs have been translated into English [Başer; Blumenthal; Grünwald 1999].

5th Amendment to the German Medicines Act which came to force in 1994 has established a simplified procedure for registration of herbal medicines, based on bibliographic data as proof of efficacy for herbal medicines with well established use. With the advent of the 5th amendment, traditional usage instead of reasonable proof of efficacy is accepted for certain category of products sold outside pharmacies. Many drugs with negative assessment by Commission E had a chance to be registered provided they are labelled as "traditionally used". Unlike, herbal medicines, the quality dossiers of "traditional" products are not checked by the health authority [Stott & Zhang].

In France, the Ministry of Health published a guideline in 1987 to give a better defined status to herbal medicines and drew up a positive list of plant drugs for registration via an abridged dossier. Historical proof of the long term widespread traditional use and their well established use in self-medication were taken into account for establishing safety with an optimum benefit to risk ratio. In 1990, the guideline was completed to include clauses on marketing authorization of new products and validation of products already in the market. This guideline includes a list of 174 plants or plant parts with approved therapeutic indications, and a list of 35 accepted therapeutic indications for minor ailments. Moreover, a list of fixed combinations of plants was given for laxative herbs. The guideline also includes a

list of toxicological recommendations and rules for labelling and packaging of herbal medicines [Başer].

The European Scientific Cooperative on Phytotherapy (ESCOP) has published 50 monographs on the most commonly used herbal drugs in the manufacture of herbal pharmaceuticals in Europe.

The strong renewal of interest in herbal medicines in Europe has necessitated the harmonization of standards in EU countries. European Pharmacopoeia (EP) has been charged with the task of preparing monographs on plant drugs. Group of experts No.13 is responsible for this task. The heavy workload of the group has forced the authorities to divide the workload of the group into two: 13A and 13B. Each group consists of around 15 pharmacognosists from member states and they meet three times a year in Strasbourg, France to continue their work on herbal monographs. Monographs on 101 plant drugs and essential oils have been prepared and published in EP 2000 (Annex 3). Work on a great number of plant drugs are ongoing in both groups and proposals for new monographs are not uncommon. The Expert Groups 13A and B, have recently been working on the preparation of a "*Guide for the elaboration of monographs on herbal drugs and herbal drug preparations*" which will be the basis for the future development of monographs [Franz; Vlietinck].

The situation in developing countries is quite different. There is hardly any legislative criteria to establish traditionally used herbal medicines as part of the drug legislation.

WHO Guidelines on Herbal Medicine

WHO has developed policies and guidelines for the recognition and utilization of proven traditional medicines and their incorporation into national drug policies and regulatory measures. The declaration of Alma-Ata was a pioneering effort on this issue. The World Health Assembly (WHA), in 1989, urged member states to 1) make a comprehensive evaluation of their traditional systems of medicine; 2) make a systematic inventory and assessment (preclinical and clinical) of the medicinal plants used by traditional practitioners and the general public; 3) introduce measures for the regulation and control of medicinal plant products and for the establishment and maintenance of suitable standards; 4) identify safe and efficacious medicinal plants, or remedies derived from them for inclusion in national formularies or pharmacopoeias [Stott & Zhang].

The 44th World Health Assembly of 1991 recommended that WHO should collaborate with its member states to review their national policies, legislations and decisions on the nature and extent of the use of traditional medicine in their health systems.

Guidelines for the assessment of herbal medicines drafted by a WHO consultation in June 1991 in Munich, Germany were adopted for general use by the 6th International Conference on Drug Regulatory Authorities (ICDRA) held in October 1991 in Ottawa, Canada. These guidelines were produced to assist national regulatory authorities, scientific organisations and manufacturers in the submission and assessment of the documentation and dossier in respect of herbal medicines. The basic criteria in the assessment was documented traditional use of such products taking into account their medical, historical and ethnological aspects [Anon. 1991].

In 1993, the WHO Regional Office for the Western Pacific published guidelines for evaluating the safety and efficacy of herbal medicines [Anon. 1993[2]]. Goals for the preparation of these guidelines were defined as

- To strengthen research in the evaluation of the safety and efficacy of herbal medicines.
- To strengthen and promote their rational use.

The guidelines were prepared to fulfil the following objectives:

- To ensure the safety and efficacy of herbal medicines used in the health care systems of countries within the region and elsewhere.
- To provide research criteria for evaluating the safety and efficacy of herbal medicines and to propose a basis for the member states to develop their own research guidelines for the study of herbal medicines.
- To facilitate the exchange of research experience and other information so that the body of reliable data for the validation of herbal medicines can be accumulated.

In 1994, the WHO Regional Office for the Eastern Mediterranean published guidelines for formulation of national policy on herbal medicines [Anon. 1994]. Main objectives of the guidelines included:

- The recognition of traditional medicines as an integral part of national health care systems.
- Cooperation between modern and traditional medicine.
- Promotion of the rational use of herbal products.
- The introduction of quality assurance systems.
- Guaranteeing of the regular supply of traditional medicines and their raw materials.

It was also recommended that a National Expert Committee be established in each country to

- draw up a national list of essential herbal medicines,
- prepare guidelines on registration requirements,
- advise on national licensing system,
- advise the Ministry of Health on drafting of a national policy on herbal medicines.

The elaborate list of issues covered in the guidelines detailed the steps to be taken to determine policies on wild collection, utilization, cultivation, local processing, etc. of medicinal herbs with the aim to manufacture quality drugs and pharmaceutical preparations.

Following the resolutions of a WHO Consultation on WHO Monographs on Selected Medicinal Plants held in 1996 in Munich, Germany, Vol. 1 of the intended series was printed and distributed in 1999. The book contains detailed monographs of 28 herbal drugs. Each monograph includes definition, synonyms, vernacular names, botanical description of the plant, organoleptic properties, macroscopical and microscopical characteristics of the whole and the powdered drug, geographical distribution of the species, general identity tests, purity tests, main chemical constituents, dosage forms, approved and traditional medicinal uses, pharmacology, clinical pharmacology, contraindications, warnings, precautions, adverse reactions, posology and references [Anon. 1999] (Annex 2).

World-wide regulatory situation of herbal medicines is reviewed in the WHO publication published in 1998 [Stott & Zhang].

The Situation in Turkey

In Turkey, serious attempts were made in 1985 to regulate herbal medicines. A National Registration Committee for Herbal Medicines was established by the Ministry of Health to draft regulations for the registration of herbal remedies. Based on the approved rules and regulations published in 1986, pharmaceutical companies submitted dossiers of their products for registration. The Committee which consisted of 3 pharmacognosists, 2 pharmaceutical technologists, 1 pharmacologist and 1 toxicologist authorized the registration of some 40 products, mostly herbal teas, with indications in its life time. These products were registered for sale in pharmacies only. The application dossier included information on plant drugs with Latin binomials, the manufacturing process, analysis and quality control methods, stability tests, pharmacological and toxicological information, indications, contra-indications and the package leaflet [Başer et al; Stott & Zhang].

The expert Committee also recommended in 1985 the Ministry of Health to ban the sale of about 70 poisonous drugs and chemicals in aktar (herbalist) shops. The decree issued by the Ministry banned the sale of suggested poisonous drugs, required each aktar shop to register at the regional office of the Ministry, made it compulsory to put up a list of drugs sold in the shop with Turkish and Latin names, and allowed them to sell permitted drugs in closed containers. Aktars are not allowed to mix drugs to make compound mixtures [Başer et al].

However, the Expert Committee was short-lived. Frequent replacements of the Ministers of Health in late 1980s caused sudden changes in policies of the Ministry, and functions of the Committee were first disrupted , then frozen and finally the Committee was abolished in early 1990s. Since the Pharmacy Departments in the regional offices of the Ministry were also abolished, inspectors of the Ministry failed to inspect aktars and, although the decree is still in force, aktars do not bother to register with the Ministry anymore, and they are not bothered by the Ministry. On the positive side, the decree brought order to their practices and taught them to observe hygiene in their premises.

Recently, the Ministry of Health has introduced new regulations for the registration of herbal medicines for sale in pharmacies. As before, the applicant has to submit a similar dossier on the product. If the product has not been tested clinically, the label has to carry the following disclaimer: *The effect of this product stems from its traditional use. Its safety and efficacy have not been verified with regular clinical trials.*

Requirements for the manufacture of herbal medicines

Good Quality Plant Materials

The first and foremost requirement for the manufacture of a good quality plant medicine is the availability of good quality, correctly identified plant material. The best way for obtaining plant material of acceptable quality for pharmaceutical production is to cultivate the best yielding strains of the plant. However, due to reasons such as unsuitability of the plant for cultivation, paucity of demand, lack of economic feasibility, etc. most medicinal plant materials are wild crafted, that is, they are collected from wild sources. Wild crafting, however, is criticised as a threat to the conservation of biological diversity. Although the concept of bioprospecting has been invented to explain and justify the benefits to be derived from nature by sustainable utilization of the environment, conservationists are solidly against wild crafting of herbs. Even though, deforestation, overgrazing of pasture lands, urbanisation of the countryside, development of tourism in and around natural reserves and land erosion

are bigger threats to biodiversity, when huge volumes of wild crafted plant materials appear in export statistics public concern becomes unavoidable.

Wild harvesting of medicinal and aromatic plants is practiced mainly in developing countries where it is carried out by peasants. These poor fellows see it as an extra income and compete with their fellow villagers to make a bigger harvest. Collected plants are dried in open air and a certain degree of wilting (if necessary), sorting and cleaning is done before packaging for transport. If the harvest is done by skilled workers, wastage of materials and destruction to the environment can be kept at a minimum. Otherwise, the magnitude of destruction may be frightening. Main *don't dos* are as follows: 1) harvesting too early, 2) hand picking of herbs, 3) inappropriate drying, 4) unsuitable packaging, 5) deliberate or undeliberate adulteration.

Good Harvesting Practice (GHP)

Rejection of the consignment by the buyer means immediate loss to the collecting party. It may not be possible to remove dirt and foreign plant materials from the chopped or semi-powdered bulk of plant material. It is not only a loss for the collector but also for the country. Therefore, a set of guidelines has been proposed with the title *"On the Commercial Collection of Plant Material from the Environment for Medicinal Purposes"*.It is also named as *"Good Harvesting Practice (GHP)"* (Annex 4).

It is aimed at educating the collectors and by introducing checks and rules for harvest and post-harvest practices, it is intended to reduce avoidable losses and to secure the collection of the correct plant material in a sustainable fashion. It requires supervision of the collectors by a responsible person knowledgeable in the particular plant harvested, its vegetative cycle, population density, correct time and mode of harvesting, etc. He educates the collectors on the recognition of the true plant, on the aspects of conservation and legal restrictions and in ways to safeguard the production of high quality plant material suitable for pharmaceutical manufacturing. It is hoped that the drug collecting organizations will soon reorganize themselves to adhere to these guidelines and a certain certification scheme will be developed to encourage and ensure that the rules laid down in the guidelines are strictly followed, fulfilled and documented. The preparation of the guidelines is timely since the Subgroup on Herbal Medicines of the European Medicine Evaluation Agency (EMEA) requires for herbal materials the minimum standards set for synthetically manufactured active pharmaceutical materials. Proof for such a standard can be obtained by legally binding written documentation indicating that the true plant material is harvested, processed, transported and stored in an orderly manner. Since the guidelines were drafted by an industrial manufacturer of herbal medicines, realizing the fact that some order is necessary in obtaining pharmaceutical quality plant materials from wild sources, there is a good chance that the GHP will soon set the minimum standards in the trade of wild crafted herbs [Harnischfeger].

Assessment of the Quality of Herbal Medicine

Health authorities would like to assess the validity of claims that a given traditionally used herbal medicine is said to possess. In assessing the safety and efficacy of a herbal preparation, the first step would be to make a literature survey in order to see whether there is any information published on the said medicine or one or more of its ingredients. The second step would be to check the validity of the information. If no data is available, the literature searches may be extended to closely related species. Abstracted information should never be used and always the original document should be consulted. Botanical identity of the plant material(s) should be confirmed and the correct plant part(s) should be used in the preparation

of the medicine. Traditional processing techniques or their modern simulations should be followed as much as possible.

General or specific quality control tests based on the main active compound or the group of compounds should be conducted. Ingredients and the finished product should conform to specified standards.

The absence of any reported toxicity is not enough to regard a traditional medicine as safe. A series of acute and chronic toxicity tests may be necessary if toxicity information is not available for any of the ingredients. If long term safe traditional use is not documented or is doubtful, then, toxicity tests should be performed.

Further toxicological studies such as renal dysfunction, hepatotoxicity, immunotoxicity, genotoxicity, carcinogenicity, reproductive toxicity should be conducted only if serious side effects are reported.

In cases where traditional use in humans has not been established, clinical trials are necessary. They are also required in the case of a new indication of an existing herb or medicine or a different dosage form or route of administration.

The catch-phrase of our time is standardization. Good Manufacturing Practice (GMP) is recognized and followed by all over the world for the manufacture of pharmaceuticals. Good Agricultural Practice (GAP) has set the standard for plant cultivation practices. Good Laboratory Practice (GLP) is aimed at setting minimum standards for laboratories to perform tests and analyses. Good Clinical Practice (GCP) is intended to lay down ethical principles to be followed while conducting clinical research on human subjects.

Adoption of these standards is enough safeguard to provide the public with good quality herbal medicines. Armed with these tools, the regulatory authorities in developing countries may adapt them to introduce legislations most suitable for their countries. Without such measures and minimum requirements a desired provision of health to the public is not possible. A practical way to fulfil these requirements may be to set up a permanent National Expert Committee on Herbal Medicine to draft legislations, monitor their implementation, and advise the Ministry of Health on issues related to herbal medicine. The Committee should consist mainly of pharmacognosists, together with pharmaceutical technologists, pharmacologists and toxicologists with knowledge and experience in the manufacturing and use of herbal medicines. The Committee may short list the most effective and easily available medicinal and aromatic plants of the country, and recommend their safe uses as home remedies for mild conditions, as herbal teas, etc. The Committee may draft guidelines for inspecting plant drug dealers and shops to ensure the sale of correct and good quality herbal drugs.

Many essential oils are highly powerful antibacterial and antifungal agents. The production and use of suitable essential oils can be encouraged where food hygiene and personal hygiene are major concerns. In Turkey, the aromatic water of oregano oil production is widely used orally as a home remedy to alleviate gastrointestinal problems, to reduce blood cholesterol and glucose levels, and to treat cancer.

Conclusions

I have tried to summarise the current situation in the world as regards the utilization of medicinal and aromatic plants and expressed my thoughts on this important issue. It is clear that the upsurge of interest in herbal medicines will continue and expand not only in the developing but in the developed world as well. Developments in industrialized countries are

more striking. Each country has a different approach to regulate plant-based medicines and especially in EU countries harmonization efforts are made and the European Pharmacopoeia is seen as a common medium for harmonization. The increasing number of monographs in EP is encouraging and a good sign for the future development of this sector. World Health Organization has been the most active UN body in the field. This organization has published many guidelines to assist regulatory authorities mainly in developing countries to introduce regulations and legislations to incorporate herbal medicines in health care. More recently, WHO has started publishing a series of monographs on herbal drugs.

All these efforts clearly show that health authorities in every country have to make sure that the people are provided with safe and effective medicines. False claims and quackery cannot be tolerated. Modern medicines are expensive and people in developing countries do not have easy access to them. Herbal medicines seem to be the most logical solution to the problem due to their time-tested safety and efficacy record. However, their prescription and supply through unauthorized people may cause complications instead of alleviating health problems. Therefore, pharmacists should be responsible for the manufacture and sale of herbal pharmaceuticals. National Expert Committee on herbal medicines should be established and preparation of traditional or herbal pharmacopoeias should be encouraged. Regulatory authorities should take action in their respective countries to adopt, adapt or formulate suitable regulations to incorporate medicinal and aromatic plant based medicines in health care systems.

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Annex 1

Worldwide Sales Figures of Herbal Remedies
1999 < 2002

[By J.Gruenwald, ICMAP News, No. 7, 10-11 (June 2000)]

Retail Price (Billion US$)	**1999**	**2002**
Europe	7.00	8.90
Asia	5.10	6.00
Japan	2.20	2.90
North America	3.80	4.50
Austral-Asia	0.12	0.14
Africa + Middle East	0.19	0.21
Latin America	0.60	0.83
Eastern Europe	0.37	0.40
Rest of the World	0.20	0.30
Total	19.58	24.18

Annex 2

Plant Drugs Contained in WHO Monographs on Selected Medicinal Plants Vol. 1

Bulbus Allii Cepae	Bulbus Allii Sativi	Aloe	Aloe Vera Gel
Radix Astragali	Fructus Bruceae	Radix Bupleuri	Herba Centellae
Flos Chamomillae	Cortex Cinnamomi	Rhizoma Coptidis	Rhizoma Curcumae longae
Radix Echinaceae	Herba Echinaceae Purpureae	Herba Ephedrae	Folium Ginkgo
Radix Ginseng	Radix Glycyrrhizae	Radix Paeoniae	Semen Plantaginis
Radix Platycodi	Radix Rauwolfiae	Rhizoma Rhei	Folium Sennae
Fructus Sennae	Herba Thymi	Radix Valerianae	Rhizoma Zingiberis

Annex 3

Plant drugs included in EP 2000

Absinthii herba
Acaciae gummi
Acaciae gummidispersione desiccatum
Agar
Alchemillae herba
Allii sativi bulbi pulvis
Aloe
Althaeae radix
Amygdalae oleum
Amygdalae oleum raffinatum
Anisi aetheroleum
Anisi fructus
Anisi stellati fructus
Arachidis oleum
Arachidis oleum hydrogenatum
Arnicae flos
Aurantii amari floris aetheroleum
Balsamum peruvianum
Belladonnae folii extractum siccum normatum
Belladonnae folium
Belladonnae pulvis normatus
Betulae folium
Boldi folium
Calendulae flos
Carvi fructus
Caryophylli floris aetheroleum
Caryophylli flos
Centaurii herba
Chamomillae romanae flos
Cinchonae cortex
Cinnamomi cortex
Coriandri fructus

Crataegi folium cum flore
Crataegi fructus
Digitalis purpureae folium
Eucalypti aetheroleum
Eucalypti folium
Foeniculi amari fructus
Foeniculi dulcis fructus
Frangulae cortex
Gentianae radix
Gossypii oleum hydrogenatum
Graminis rhizoma
Hamamelidis folium
Harpagophyti radix
Helianthi annui oleum raffinatum
Hyoscyami folium
Hyperici herba
Ipecacuanhae radix
Lavandulae aetheroleum
Levistici radix
Limonis aetheroleum
Lini semen
Liquiritiae radix
Lupuli flos
Matricariae flos
Maydis amylum
Maydis oleum raffinatum
Menthae piperitae aetheroleum
Menthae piperitae folium
Millefolii herba
Myrrha
Olivae oleum
Olivae oleum raffinatum
Olivae oleum virginum
Opium crudum
Orthosiphonis folium
Oryzae amylum
Passiflorae herba
Plantaginis ovatae semen
Plantaginis ovatae seminis tegumentum
Polygalae radix
Primulae radix
Psyllii semen
Rapae oleum raffinatum
Ratanhiae radix
Rhamni purshianae cortex
Rhei radix
Ricini oleum
Salviae officinalis folium
Sambuci flos
Sennae folium
Sennae folium extractum siccum normatum
Sennae fructus acutifoliae
Sennae fructus angustifoliae
Sesami oleum raffinatum
Sojae oleum
Sojae oleum hydrogenatum
Solani amylum
Stramonii folium
Thymi aetheroleum
Thymi herba
Tiliae flos
Tormentillae rhizoma
Tragacantha
Tritici aestivi oleum raffinatum
Tritici aestivi oleum virginale
Tritici amylum
Uvae-ursi folium
Valerianae radix
Xanthani gummi

Annex 4

Proposal for a guideline on the commercial collection of plant material from the environment for medicinal purposes
(GHP, Good Harvesting Practice for Collected Plant-Material)
[By G.Harnischfeger, ICMAP News, No.7, 12-14 (June 2000)]

The following guideline describes requirements, which should be met in today's collection of medicinal plant material. Observance of this guideline constitutes an important step towards medicinal plant products of constant and sufficient quality.

Since demand for herbal starting material from a specific species is difficult to predict and climatic conditions influence greatly its quality, it is prudent for the trader or buyer to include as many different growing areas as possible. This allows equalization of quality by mixing individual batches of different provenances.

1. Collecting Personnel

1.1 Collectors should possess extensive knowledge about the identification of the plant from which the drug is derived, its physiological specifics and its requirements for environmental factors like shade, moisture, soil etc.
1.2 Collectors should be able to distinguish clearly between the medicinal plant and its closely related relatives in order to avoid unwanted admixtures.
1.3 Collectors should have sufficient knowledge about optimum conditions for the time of harvesting, the best techniques for harvesting and also enough knowledge about the subsequent conservation process and storage conditions to insure high quality of the raw material gathered.
1.4 Collectors should adhere to a high degree of personal hygiene. They should not take part in collecting activities if suffering from infectious diseases transmittable by food, e.g. diarrhea, carry open wounds, inflammations of the skin etc. until their complete recuperation.
1.5 The knowledge of the collectors should be periodically reinforced and monitored by a competent specialist of the collecting organization. This education process should be documented.

2. Collecting

2.1 Collecting should take place at a time when the plants with regard to their use are in optimum condition with respect to required pharmaceutical quality and therapeutical efficacy.
2.2 Collecting should take place under dry conditions. Wet soil, dew, rain or exceptionally high air humidity are unfavorable.
2.3 All equipment used should be clean and free of remnants of previously harvested plants.
2.4 Mechanical damage that results in undesirable quality changes has to be avoided, e.g. loss of essential oil in broken umbelliferous fruits.
2.5 Whenever possible collection should take place in such a way, that unnecessary damage to the plant is avoided. Care should be exercised to enable the plant to grow back to a normal state.
2.6 The period between collecting and arrival of the plant-material at the drying facility should be reduced to a minimum in order to avoid undesirable changes in external appearance, quality and microbial status.
2.7 The collected plant-material should be protected from pests, pets and domestic animals.

2.8 Special care should be taken to avoid over harvesting and through it the danger of extinction of the plant species in the particular collecting area.
2.9 No plants or parts of plants on the endangered species list, be it local or international, should be collected unless special permission is given by the competent state authorities.
2.10 The responsible collecting organization has to appoint at the local level a person charged with insuring the correct identification of the collected plant-material and the compliance of the collectors with provisions 2.1 - 2.9
2.11 Information about the general area of collection, for example, a brief description of habitat, climate, soil type and other specifics which might influence the quality of the harvest should be documented by the responsible collecting organization for each campaign.
2.12 Appropriate documentation including season and date of the collecting campaign and an assessment on identity, macroscopic quality and purity of the collected plant material should accompany every shipment from the collecting area to the drying and/or processing facility.
2.13 Every shipment constitutes a batch. It should be labelled appropriately and be accompanied by the documentation outlined in paragraph 2.12.
2.14 The appointed person of paragraph 2.10, possessing adequate knowledge about the requirement on identity, quality and purity of the plant-material should sign the accompanying documentation and accept responsibility for those specifics named in paragraphs 2.12 and 2.13.

3. Drying/Processing

3.1 Arriving at the drying/processing facility the collected plant-material has to be promptly unloaded and unpacked. It should not be exposed to the sun and must be protected from the elements.
3.2 Building-facilities used for drying/processing must be clean, well aerated and never be used for animal keeping.
3.3 Building-facilities must provide protection of the plant-material against pests, rodents, insects and birds as well as against pets and domestic animals.
3.4 Equipment like drying-frames etc. must be clean and regularly serviced.
3.5 In case of air-drying, the plant-material should be spread in a thin layer. The drying frames must be located in a sufficient distance from the ground to provide adequate air circulation and facilitate uniform drying.
3.6 For all methods used, adequate consideration should be given that drying conditions are chosen appropriate to the type of plant-material processed. These concern both the character of the active ingredients (*e.g.* essential oils) and the type of plant organ collected (*e.g.* root, leaf, flower etc.).
3.7 Drying directly on the ground under exposure to sunlight should be avoided.
3.8 The dried drug should be screened in order to eliminate discolored, moldy or damaged pieces and foreign admixtures and contaminants.
3.9 Clearly marked waste bins should be kept ready, emptied and cleaned daily.
3.10 The dried plant-material should be packaged immediately in bags or containers permitting air exchange in order to reduce the risk of pest attacks and mould.
3.11 Adequate documentation of the drying process, duly signed by a responsible person, should be added to the batch report.

4. Packaging, equipment, facilities for storage, documents and quality assurance

The requirements laid down in the Good Agriculture Practice (GAP) guidelines apply where appropriate.

REGULATORY CONSIDERATIONS OF HERBAL MEDICINES

INTRODUCTION:

I would like to express my profound gratitude to the organizers for inviting me to participate in this workshop. I consider the workshop very timely and relevant especially with the renewed global interest in the search for remedies from plant sources for emerging diseases that currently have no known cure.

Medicinal plants and their preparations have been used since the earliest history of mankind and have formed one of the foundations for healthcare in virtually all cultures throughout the world. The use of herbal remedies is an integral part of traditional medicine, which is practiced in different forms in Nigeria as elsewhere. In spite of their long tradition of use as medicinal products, public's interest in herbal remedies is still growing with particular emphasis on their clinical, pharmaceutical and economic value. There is a significant shift from the use of orthodox medicines to herbal medicinal products globally and this trend is similarly observed in Nigeria. In many rural communities in Nigeria and other developing countries the use of herbal remedies forms an important component of primary healthcare and in some cases the only form of healthcare accessible.

In recognition of this fact, the WHO over the years has been playing a major role in the promotion of traditional medicine. Accordingly, WHO resolution WHA42.43 of 1989 urged member states to introduce measures for the regulation and control of medicinal plant products and for the establishment and maintenance of suitable standards. The International Conference on Primary Healthcare, held in Alma-Ata, USSR, in 1978, recommended inter alia, the accommodation of proven traditional remedies in national

drug policies and regulatory measures. In pursuance of its various resolutions the WHO had prepared guidelines for the assessment of Herbal Medicines by member states to assist national regulatory authorities, scientific organizations, and manufacturers to undertake an assessment of the documentation/ and dossiers in respect of such products. These guidelines provide basic criteria for the assessment of quality, safety and efficacy and requirements for labelling of herbal medicinal products.

REGULATION OF HERBAL MEDICINES

In spite of the importance of herbal medicines to healthcare delivery not much attention had been given to their regulation and control. This poses public health problems regarding the quality, safety and efficacy of the products. The public is also exposed to toxic substances resulting from either some inherent property of the product or possible adulteration of the herbal preparations with potential toxic substances. For these and other reasons, it is necessary to regulate the production and use of herbal medicines in all countries.

Responsibilities of Regulatory Authorities:

The basic responsibilities of a regulatory authority are to ensure that all products subject to its control conform to acceptable standards of quality, safety and efficacy, and that all premises and practices employed to manufacture, store and distribute these products comply with requirements to ensure the continued compliance of the products with these standards until they are delivered to the end-user. These responsibilities are being carried out in respect of pharmaceutical products in most countries but the same cannot be said of herbal medicinal products, as their control had not been given adequate attention. The situation is, however, changing and many countries have taken necessary steps to address the issue in the interest of public health.

In Europe, significant progress has been made with regard to licensing of herbal medicinal products, with proof of quality, safety and efficacy as basic requirements for registration. An attempt is being made of establishing a centralized system of marketing authorization, which may be extended to phytomedicines. The European scientific cooperative on phytotherapy was formed in 1989 to establish harmonized criteria for the assessment of phytomedicines to support scientific research and to contribute to the acceptance of phytotherapy at a European level. A number of herbal medicinal products have been approved for use in some of the countries.

India and china are well known examples of countries where traditional medicine has been integrated into the official healthcare delivery system and the use of herbal medicines is governed by appropriate regulatory provisions.

In the United States, most herbal health products are regarded as Dietary supplement with structural/functional or health claims permitted and therefore not subject to FDA approval for marketing authorization. On the other hand, herbal products with therapeutic claims are classified as drugs and require FDA approval.

In Africa, the organization of African Unity Scientific, Technical and Research Commission has played a leading role in promoting medicinal plant research in the region. The efforts of the commission resulted in the publication of the first edition of the African pharmacopoeia in 1985. The need to regulate the use of herbal medicinal products has been recognized by many countries in the region and appropriate regulatory measures are being put in place.

THE ROLE OF NAFDAC

The National Agency for Food and Drug Administration and Control (NAFDAC) is the regulatory authority in Nigeria. The Agency was established in 1993 with the mandate to regulate and control the importation, exportation, manufacture, advertisement,

distribution, sale and use of food, drugs, cosmetics, medical devices, bottled water and chemicals. These functions are carried out through enactment of relevant laws and regulations. I am pleased to say that the Agency had made a significant impact in its operations to justify its establishment.

As earlier mentioned, herbal medicinal products are widely used in Nigeria as part of traditional medicine practice and this trend is growing probably as a result of the current unfavourable economic situation in the country, which has made orthodox medicines, unaffordable and inaccessible to a large proportion of the population. The government has also shown a serious commitment towards the regulation of traditional medicine practice in pursuance of its National Health Policy. The recent approval of the National policy on Traditional Medicine Code of ethics and draft legislation by the National Council on Health is a significant step towards the establishment of National and State Traditional Medicine Boards to enhance the regulation of traditional medicine practice and promote cooperation and research in traditional medicine. In response to these developments, NAFDAC has taken necessary steps to regulate and control the use of these products with a view to ensuring their quality, safety and efficacy. Accordingly, the Agency in 1997, organized an International Workshop on Standardization and Regulation of Herbal Medicines in collaboration with the Bioresources Development and Conservation Programme and the West African Pharmaceutical Federation. The Workshop made far-reaching recommendations that would facilitate the regulation and control of herbal medicines by NAFDAC.

The Agency subsequently, organized a consultative meeting with experts in 1998 to develop draft guidelines for the registration of herbal medicinal products in Nigeria. This was followed by another consultative meeting comprising participants from various interest groups such as researchers from the universities and research institutes with

specialization in different areas of medicinal plant research, traditional healers, and orthodox medical practitioners. This meeting reviewed the draft guidelines earlier prepared by the previous group and produced the blue print for regulatory control of herbal medicinal products in Nigeria. This document was recently approved by the National Council on Health. The Agency has received applications for registration of herbal medicinal products and related substances and these are currently being processed for listing based on the following criteria:-

- Evidence of proven efficacy based on evaluation of documentation
- Laboratory evaluation.
- Submission of certificate of manufacture and free sale from the country of origin
- Expert opinion on the product.

The Agency will commence full registration of herbal medicinal products in line with the protocols developed recently, as the necessary facilities are already in place.

DEFINITION OF TERMS

Different terminologies and overlapping definitions exist in different countries for 'herbal product' and this was also noted by WHO in its definitions. Such terminologies include alternative medicine, phytopharmaceuticals, traditional remedies, dietary supplements, nutraceuticals, herbal remedies etc. Bearing in mind the need for simplicity and suitability and taking cognisance of our local situation, three classes of traditional medicines have therefore been defined as follows:-

Herbal Medicinal Products:

These are defined as finished and labelled medicinal products containing plant material and/or their preparations presented with therapeutic or prophylactic claims. This definition includes homeopathic preparations derived wholly or partly from plant sources.

All preparations containing a plant in part or wholly are also included. However, in Nigeria some traditional medicine preparations contain only animal or mineral material with or without plant part. In such cases, the two definitions below apply. All herbal preparations that are presented with no therapeutic or prophylactic claim are not considered as medicinal. Such are considered as cosmetics or food items.

Animal Medicinal Product:

These are defined as finished and labelled medicinal products containing only animal material and/or their preparations presented with therapeutic or prophylactic claims.

Mineral Medicinal Product:

These are defined as finished and labelled medicinal products containing inorganic minerals and/or their preparations presented with therapeutic or prophylactic claims.

CLASSIFICATION OF HERBAL MEDICINAL PRODUCTS

The following classification of herbal medicinal products has been adopted by the Agency.

Extemporaneous Preparations:

These are herbal medicinal products that should be used in a locality by the patient within a short period of a few days only. They are compounded and dispensed by the traditional medical practitioner for his own patient on a one-to-one basis in his clinic.

Any regulation for such products will be difficult to implement, as the products are not usually available for general distribution and sale. However, their documentation should be encouraged.

Large Scale Manufacture of Herbal Medicinal Products:

A large scale manufacturer produces units of a preparation in quantities beyond the usual one-to-one quantities made by a traditional medical practitioner for his own patient's use within a short period of time. Large-scale manufacture is intended for distribution to a

very wide area through other outlets and for storage for a considerably long period of time. The issues of preservation and shelf life are significant in the consideration of approval for registration of such products.

APPROVED REGISTRATION PROCEDURE FOR HERBAL MEDICINAL PRODUCTS

This is summarized as follows:

1. Application by applicant in writing
2. Payment of prescribed application fees
3. On satisfactory assessment of the duly completed application form and relevant documents, a pre-registration inspection of the production facilities of the applicant will be required for locally manufactured products on payment of prescribed fees. Documents to be submitted with completed form are as follows:
    i. For locally manufactured products
        a. Authorization as manufacturer of products to be registered
        b. Evidence of registration of applicant by relevant local competent professional body.

ii. For Imported Herbal Products:

It is necessary to apply for import permit to bring samples for registration

- Current Registration Licence of the Superintendent Pharmacist and Pharmaceutical premises issued by the Pharmacist's Council of Nigeria
- Power of Attorney issued by the manufacturer and certified by a notary public.
- Certificate of analysis of the product from country of manufacture
- Evidence of satisfactory clinical trials conducted in Nigeria

4. Dossier and samples will be submitted for all products for vetting.
5. Samples required for laboratory analysis will be submitted and prescribed processing fees will be paid.

6. On satisfactory inspection (for local products) and laboratory reports, a brief for registration of the product would be presented for consideration by the Product Registration Committee of the Agency.
7. On approval by the Committee, applicant would be required to pay the prescribed fee for the Registration Certificate, which is renewable yearly for extemporaneous preparations and every five years for the other categories of herbal medicinal products.
8. Mandatory post-marketing surveillance and reporting on the use (including adverse reactions) of the herbal medicinal product shall be required. Such report should be submitted to relevant health authority (Local Government, State Ministry of Health, Federal Ministry of Health), for forwarding to NAFDAC.
9. All advertisements (promotion) of registered herbal medicinal products must be approved by NAFDAC.

The detailed protocol for registration of herbal medicinal products is outlined in Appendix I.

OTHER CONSIDERATIONS:

I would like to briefly highlight some areas that are relevant to the development of herbal medicinal products and their regulatory control.

Research and Development (R&D)

In order to improve on the general acceptability of herbal medicines and provide them some scientific validity, concerted R&D work is needed to standardize the nomenclature, collection, extraction process, formulation procedures, quality, safety, dosage, indications, contra-indication etc. There is need to establish the actual need and appropriateness of the medicinal substances used. We must also ensure that they are rationally used and that the requirements for their use are assessed as accurately as possible. Basic criteria for the evaluation of the quality, safety and efficacy of traditional medicines need to be defined, in order to assist national and state authorities, to control and regulate them. The aim of herbal medicine R&D should be directed at providing rationale for the continued use of efficacious and safe products, and excluding inactive or toxic ones. The exercise should include field studies and evaluation. The drawback in R&D in Africa is the low funding of the R&D programmes both in the public and private sectors.

Conservation:

As demand for herbal medicine increase, pressure on the medicinal plant resources also becomes greater. Collection of wild plants for traditional medical use is extremely detrimental to the existence of certain species. Cultivation of plants in gardens or private farms must be encouraged. Alternative technology must be applied. Traditional Medicine Practitioners lack the means or know-how for large-scale cultivation of medicinal plants, but they can manage small herbal gardens in their localities. It is also absolutely necessary to design alternative ways with local traditional medicine

practitioners to harvest medicinal plants without endangering them. Major importers demanding high volumes of plant material are also contributing to the decline of medicinal plants species in Africa.

Education and Training:

Well trained practitioners of traditional medicine will greatly improve the quality of herbal products and stimulate research into many of our medicinal plants and products. It is absolutely essential to focus on the development of the right calibre of manpower for herbal medicine practice at all levels. A formal training programme should be designed to complement the hereditary mode of knowledge transfer. Such training may be organized through the relevant government institutions or Non – Government Organizations (NGO's). It may also be necessary to organize a forum for exchange of ideas and information on routine basis. This may be in the form of workshops, seminars or courses to educate the traditional healers on some important aspects of their practice and update them on latest developments.

CONCLUSION:

Mr. Chairman, I have briefly highlighted the measures that the Agency has put in place to facilitate the regulatory control of herbal medicinal products in Nigeria. This will no doubt check the current indiscriminate use and advertisement of these products and build confidence in their beneficial effects. The Agency will establish a database on herbal medicinal products with the help of compiled information on medicinal plants that have been studied in Nigeria from various research institutions in the country. A database information will also be established on poisonous plants. This will require the continued support and assistance of relevant organizations within and outside the country.

Thank you for your attention.

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PROTOCOL FOR REGISTRATION OF HERBAL MEDICINAL PRODUCTS MANUFACTURED IN LARGE SCALE

GENERAL INFORMATION

A large scale manufacturer produces units of a preparation in quantities beyond the usual one-to-one quantities made by a traditional medical practitioner for his own patient's use within a short period of time. Large scale manufacture is intended for distribution to a very wide area through other outlets and for storage for a considerably long period of time. The issues of preservation and shelf life are significant in the consideration of approval for registration, ... The guidelines for registration of this group of medicinal products include:-

Information about the applicant/manufacturer:

- Name and location address of the applicant (not P.O.Box)
- Name and location address of the manufacturer (not P.O. Box)
- Registered premises or marketing outlet if any
- Site description, company profile and organogram
- Particulars of registered superintendent pharmacist
- Particulars of licence of the premises used for manufacturing

Technical Information on the Products

a. Trade name of the medicinal product
b. Type and description of the medicine (herbal or animal or mineral as the case may be)

Details of plants used

Common name (if any)
Scientific name (including family and authority)
Local name (give all possible ethnic names)

Plant part used in the manufacture

- morphological parts used (leaves, stem etc)

- season of collection (dry or wet)
- geographical source (indicate place of collection)
- collected from the wild or cultivated (NB for large scale manufacturing cultivation is preferred and with organic fertilisers)
- date of collection
- condition for collection before use (fresh or dry)
- method of collection (mechanical or manual labour)

Evidence of herbarium authentication

- Three recognised herbaria/botanists to issue certificates of plant identification and authentication. Two of such certificates must tally

Ethnomedical history of the product

- Describe popularity, frequency and extent of use
- Include any relevant literature, reference monograph (Ayurveda, Chinese traditional medicine etc)

Production process

- Description of post harvest treatment
- Drying
- Pulverisation and particle size determination
- Extraction
  Solvent used
  Temperature
  Method of extraction
  Ratio of plant material to solvent
  Extraction method
- Type of dosage form (tablet, capsule, tea bags etc)
- Excipients used
- Special, unique and necessary production requirements, if any

<u>STANDARDISATION OF PRODUCTS (LABORATORY & CLINICAL)</u>

Determination of contaminants

Microbial load, moulds, Aflatoxins
Contaminant heavy metals (Pb, Hg, Cd etc)
Radioactive background
Extraneous material (insect, animal parts, stones etc)

Pharmacognostical analysis

- Microscopy (for powdered vegetable medicine)
- Extractive value (water and alcohol soluble)
- Loss on drying
- Ash value
- Acid insoluble ash

Phytochemical analysis

- Alkaloids, glycosides, saponins, tannins, flavonoids etc
- Chromatographic fingerprints (TLC, GC)

Pharmaceutical analysis

- Moisture content
- Hydrophobicity (Wetability)
- Compressibility & friability (tablet & capsule)
- Stability tests and shelf life
- Packaging material
- Any other relevant test (e.g disintegration, solubility, bio-availability etc)

Indication for the herbal medicinal product

- Indication
- Major conditions
- Contraindication(s)

Method of Use

- Dosage
- Route of administration
- Duration of treatment
- Antidote (in event of overdose)

Toxicological Profile

- Acute toxicity LD50 (at least in two species)
- Chronic toxicity
- Teratogenicity, Mutagenity, Carcinogenicity

Proof of Efficacy

- Clinical studies
- Pharmacological studies
- Literature data
- Ethnomedical history

Labelling Requirements

The following information is required

- Name of the product (not suggestive of therapeutic claim)
- Quantitative list of ingredient(s)
- Dosage form
- Directions for use (specify for children, elderly etc)
- Indications:
  - Dosage (if appropriate, specify for children and elderly)
  - Mode of administration
  - Duration of use e.g specify "if not cured within certain number of days consult your doctor"
  - Symptoms of overdose and what not to exceed
  - Contraindication
  - Warnings, if any
  - Precautions e.g "use in pregnant and lactating mothers not recommended"
- Batch number
- Manufacturing date
- Special storage conditions, if necessary
- Full location address of manufacturer
- Provision for NAFDAC registration number

CHALLENGES, CONSTRAINTS AND OPPORTUNITIES IN TRADITIONAL MEDICINE IN AFRICA

By

Professor Abayomi Sofowora

(Presented at the UNIDO/ICS/NIPRD Workshop on Strategies to Strengthen the Utilisation of Medicinal and Aromatic Plants -MAPS- in the National Healthcare System. Abuja. 11-13 July. 2000)

Throughout the entire world. interest in medicinal plants has increased tremendously in the past two decades. The untapped wealth of the plant kingdom has become a target for the multinational drug companies and research institutes for new drugs and lead compounds. Prominent in this area has been the investigation of traditional remedies, largely of botanical origin. on which a worldwide majority of the world. especially the countries of Africa still relies for its source of medicine. In addition. western cultures shave become increasingly interested in natural sources of drugs with the public at large acquiring herbal preparations from a plethora of various retail outlets. The trend is now to go back to nature for nearly all cures.

In the well established medical and pharmacy faculties and schools the tropical medicinal plants brought to the notice of the students were limited to the small number of those that have been studied and on which monographs have been written in the industrialised countries. As a result. the specialists trained in the different sciences and technologies were not suitable for their own countries in Africa since the development of these countries cannot be brought about in the absence of the knowledge of the needs of the places concerned.

More than 200.000 out of the 300.000 plants species so far identified in the world are in the tropical countries in Africa and elsewhere. Among the potential users of these plants. traditional medicine and pharmacopoeia are on top with those that practice them. that is 80% of the population of the third world.

Our continent. Africa. comprises some fifty three countries representing a population of 600 million people (McNeely. 1996) with a vast array of indigenous languages as well as the languages of their former colonial masters which are mainly English. French and Portuguese. It will not be possible. therefore. to treat all the fifty-three countries. I will. however. utilise examples from the various sub-regions in making my points.

It is important to mention that the convention on Biological Diversity as well as the World Trade Organisation Treaty both of which several countries of Africa are signatories to have played significant roles in influencing changes in the world generally. The world is changing, science is changing, Africa itself is changing and the direction of research in Africa is changing. Whether we like it or not. the scientists in Africa must change with the times. In this paper. I intend to point out how some of the changes that are taking place are affecting the research on medicinal plants. I hope that this will stimulate our discussions towards the end of this conference when we shall have heard other experts considering the detail aspects of IPR, trade. economics.

funding, biotechnology and information technology as well as biodiversity conservation issues.

An Overview of Research into African Medicinal Plants.

Ethnobotanic Surveys

Information on medicinal plants' use has been obtained from herbalists, herb sellers and indigenous people in Africa over the years (Baba *et al.*, 1992; Wondergem et al., 1989). Under the umbrella of Agence de Cooperation Culturelle et Technique (ACCT) in Paris, ethnobotanical surveys with international teams have been carried out in the following African countries: Central African Republic, Rwanda, Mali, Niger, Federal Islamic Republic of Comoros, Mauritius, Seychelles, Gabon, Dominica, Tunisia, Madagascar, Togo, Congo and Benin Republic. The Organisation of African Unity's Scientific Technical and Research Commission (OAU/STRC) has carried out similar surveys in Western Nigeria, Uganda, Cameroon, Ghana and Swaziland (Adjanohoun et al., 1989, 1993, 1996 & 1999). All these ethnobotanical surveys have been published and can also be consulted in a database recently created by the OAU/STRC in Lagos, Nigeria. The Ghana survey report is due out soon. The report for the survey of Swaziland which was carried out in 1998 is yet to be completed. Another database by Dr. Petitjean was established for the flora of the islands of Comoros, Madagascar, Mauritius, Rodrigues, Reunion & Seyschelles. Other databases on medicinal plants in the region exist such as the NARISTAN by Hoechst/Naristan used in the University of Cape Town by TRAMED. It holds over 46,000 folk use anecdotes and in-house bioactivity assays on some (350) South African plants. There is also the List of East African Plants (LEAP) available in Kenya Forestry Research Institute and the published phytochemical literature on African plants available in NAPRECA database. The Biodiversity Development and Conservation Programme (B.D.C.P.) also has an off-line database with information on the economic botany of over 1,000 African plants. Various on-line and off-line databases on wild species useful for food and agriculture are now available for sourcing information on plants growing in Africa (Thormann et al., 1999). More ethnobotanical surveys on the region are still being carried out and published.

Phytochemical and Biological Screening of Medicinal Plants

As far back as 1968 it was decided at a conference organised in Dakar by The OAU/STRC that the efficacy of herbs used by TMPs should be tested in order to find proofs for the efficacies claimed for them. The areas to be given priority were: anticancer, antimalarial, anti-helminthic, antimicrobial, antihypertensive, cardiac activity, antisickling and antiviral. That decision was taken at the time because very little research was being carried out on African medicinal plants as such. What research that was undertaken was merely to look at the chemistry of the constituents of plants generally (especially as logs) to find the chemicals responsible for their desirability as furniture or resistance against pest attack. The OAU/STRC funded 17 research centres all over Africa in order to stimulate research in this new direction of proof of efficacy of medicinal plants. The following are highlights of the researches to

date as depicted by publications on African medicinal plants as collated by NAPRALERT database for natural products. Now, some 30 years later, only 36% of all the publications from 1988 - 1996 dealt with bioassay guided isolation of plant constituents as well as their pharmacological and toxicological testing. The others dealt with purely phytochemical research (including quantitative analysis). Out of the biological screening work 16% resulted in publications on antimicrobial activity in 1993 rising to 21% in 1996; molluscicidal, 11% down to 4% by 1996; antimalarial, 7% remaining steady; toxicity testing 7% remaining steady; antitumour related, 4% also remaining steady. Malaria in Africa directly accounts for one million deaths a year, mostly in children under five years of age and it may account for many more as a contributing factor to deaths assigned to other causes (WHO, 1996). This fact, together with increased interest by WHO-TDR in this area, is probably the reason for the sustained level of research and the publications in this area (Keita 1996; Paulo et al., 1996). By 1996, two new areas of biological testing appeared to be on appreciable increase, namely: anti viral now 6% and anti-inflammatory now 4%. Activities reported in these two areas were hitherto too small. 56% of the antiviral activities reported were specifically for anti-HIV. This was probably due to the increased interest caused by the availability of *in vitro* tests. In molluscicidal testing, three plants came out as having potential commercial exploitation, namely *Phytolacca dodecandra, Swartzia madagascariensis* and *Tetrapleura tetraptera*. The field trials on these and toxicity studies against non target organisms have been carried out successfully in ponds where the intermediate host snail of schistosomiasis is prevalent (Hostettmann, 1989; Adewunmi, 1991; Amusan, Msonthi & Makhubu, 1995). The drop in the search for plant molluscicides since 1993 could be due to the development of these three together with the fact that the control of schistosomiasis itself cannot rely on the use of molluscicides alone. Research publications on veterinary use of medicinal plants and to treat diabetes, hypertension and ulcer are on the increase but are not yet sufficient to worth detail mention (Farnsworth, 1997).

Certain researches on medicinal plants have also come close to industrial application or have hit the headline news at international and national levels. One cannot mention all of these but a few will be cited here.

The research and development work by the Nigerian team on the use of 'Fagara' in managing sickle cell anaemia is one of such. The active ingredients were characterised after demonstrating in vivo the antisickling activity of the root of *Zanthoxylum zanthoxyloides*. Various R&D efforts on this finding were published including the standardisation work and this led to the inclusion of this plant as 'Fagara' in the African Pharmacopoeia (1995). Similarly, R&D works on *Cryptolepis sanguinolenta* by Tackie *et al* in Ghana (at the Centre for Research into Plant Medicine in Mampong-Akwapim) has led to the isolation of the active ingredients and pharmacological and toxicological studies along with the standardisation work on this plant. Th subsequent findings led to its inclusion in the Pharmacopoeia of Ghana. The work of Iwu *et al.* on *Garcinia kola* led to a patent on the 'kolaviron' isolated from it for use as an hepatoprotective agent while the work of Msonthi's team in Malawi on *Hypoxis nyasika* led to the patenting of nyasoside for treating uterine cancer. The collaboration of Cameroonian scientists with NCI researchers on the antiviral activities of *Ancistrocladus korupensis* led to the isolation of the Michelamine B with high possibility for its use in the management of HIV/AIDS. However, the low

therapeutic index observed in the primate studies in NCI (USA) on this alkaloid lead to its present low rating as an anti-HIV drug in the NCI's drug development programme. The work of Professor Kanyerezi of Uganda on preparations from TMPs for treating people living with (PLW) HIV/AIDS has led to a herbal product that improves the CD4 count of AIDS patients. Dr. Kabatesi of Kampala also identified TM recipes that relieve people living with HIV/AIDS of diarrhoea and vomiting. The research of Professor Wambebe's team in NIPRD Abuja, Nigeria led to the advent of the medicinal plant product: NIPRISAN for the management of sickle cell anaemia. That marked an important change in direction for research on the continent. Whereas the earlier researches mentioned went through a period of publish or perish among scientists in Africa the current trend is to patent or perish. Data accumulated on NIPRISAN up to the multi-centred phase 2 clinical trials going on in Nigeria are used to strengthen the patent protections already filed in some 40 countries by UNDP on this plant product.

Research and development work on medicinal plants has great prospects because of the possibility of finding new chemical agents to treat new diseases coming up, or to find rich sources for already known drugs or for finding new molecules that can serve as ten-plates for the synthesis of drugs. Africa being rich in biodiversity in plants is therefore a fertile ground for bioprospecting and our countries should be alert to the prospects of earning good incomes to augment our ailing economies through signing proper agreements with appropriate prospecting companies but in line with the CBD protocols. There are problems in this exercise, however. This is because many researchers from the north, under the guise of research collaboration, are literally stealing African plants and developing them through R&D to a point that the country of origin is not benefiting at all or is getting only very little kick-backs out of such collaborations. The sad part of this is that some African scientists are being used to perpetrate this exercise without knowing it. Other African scientists that should know better are deliberately selling African bio-resources cheaply to the north and depriving our continent of the necessary benefits from this rich natural resource which is all we have got. We should be on the look out for the bio-pirates in whatever form they come.

Collaboration in R & D on Medicinal Plants in Africa.

The creation of the Natural Products of East and Central Africa (NAPRECA) network by UNESCO has given a boost to inter-African collaborative research efforts on medicinal plants in that sub-region of Africa. This led to the creation of the West African network (NAPRWA) also with UNESCO support. The International Organisation for Chemistry in Development (IOCD) has encouraged the creation of a Network of Analytical and Bioassay Services in Africa (NABSA) with the co-ordinator as Professor Berhanu Abegaz of the Department of Chemistry, University of Botswana. This network was created to encourage bioassay of natural products from phytochemical research by pooling existing analytical facilities in African research laboratories. Services offered include NMR (proton & carbon), polarography, MS, GC/MS, IR, UV-Vis, GC, HPLC, anti-feedant, larvicidal and brine shrimp assays. Our team in Ife hopes to add antisickling and antimicrobial testing to this network facility soon. The co-ordinator receives all requests for analysis and

passes them on to the appropriate laboratory where the facility exists among the collaborating laboratories in Africa.

At the initiative of the Commonwealth Science Council in 1996, a network for Southern African Plant Resources Exploration etc. (SAPR-E) was established for the documentation and sustainable exploitation of plant resources in that sub-region through collaborative effort between scientists and institutions in Southern Africa. The meeting was held here in the University of Swaziland. Dr. A. Gurib-Fakim of the Department of Chemistry, University of Mauritius was identified as the co-ordinator. All these efforts are expected to boost output in R & D work in Africa in the field of medicinal and aromatic plants and should increase the prospects of more phytomedicines.

Inter-African cooperation

The development of the first African pharmacopoeia is a good example of inter-African co-operation in this field of research on medicinal and aromatic plants. A committee of African scientists got together over a period of time, collated data and compiled the African pharmacopoeia that was published by the OAU/STRC (1985 & 1986).

A fair amount of co-operation takes place also through the training of individuals at high level manpower for research on medicinal and aromatic plants. The OAU/STRC has provided fellowships for such training at the departments of pharmacognosy at Cairo University (Egypt) and Obafemi Awolowo University in Ile-Ife (Nigeria) over the past fifteen years or so. Students from Nigeria, Tanzania, Ghana, Ethiopia, Sierra Leone and Cameroon have benefited from such co-operation facilitated by the OAU/STRC. Several other African scientists were trained in the University of Ibadan's department of chemistry, the Makerere University and the Addis Ababa University's department of chemistry for researchers in the East and Central African sub-region. A few scientists outside of that sub region also enjoyed such facilities which were financed by IFS, UNESCO, DAAD or other funding agencies (Noamesi et al., 1990).

Also the shortage of equipment and reagents for research had forced some scientists to send their plant material to Europe and the USA for analysis in the past. This trend should go down with the establishment of networks like NABSA. The intention of these networks is not to stop collaboration with scientists in the developed countries completely. No. The idea is to strengthen capabilities in African laboratories so that, at least, screening can be carried out in these laboratories whilst the more complicated work of detailed analysis can form the basis for future collaboration if need be and if help is not available in Africa. African scientists will then add value to the plant they ae working on before they get into a real collaborative venture rather than be treated merely as plant collectors in R & D work on medicinal plants.

Trade in and Cultivation of Medicinal Plants in Africa

The ultimate goal of any research on medicinal plants is to develop the plants or active ingredients into forms in which they can be used by our peoples through

formulation studies, pilot scale and industrial scale manufacture of the developed medicinal plants products. The large scale use of medicinal plants and their products necessitate the cultivation of the plants in large scale and should result in inter-African trade on medicinal plants as well as their exports to outside Africa. Not all plants can be cultivated directly without loss of the desired active ingredients. Research in the field of cultivation of medicinal plants in Africa needs to be intensified therefore.

The amount of trade going on in the area of medicinal plants in some African countries is well documented (see Table 1) but not in all cases. It is known, for example, that the government of Cameroon is the major source to the world market of *Prunus africana* bark, where it has been harvested since 1972. From 1986 to 1991, 11,537 metric tons of the bark (reaching an average of 700 tons p.a.) were processed by Plantecam Medicam, a French owned company based in south-west Cameroon. *Prunus africana* bark represents 88.6% of the medicinal plants exported by this company between 1985 and 1991 (Cunningham and Mbenkum, 1993). The bark is used in treating prostrate gland hypertrophy and benign prostrate hyperplasia (Andro & Riffaud, 1995). Another major plant exported by Cameroon is the seed of *Voacanga africana* (Apocynaceae) which is used for the production of the alkaloid tabersonine used as a CNS depressant in geriatric patients. Cameroon exported $40 million worth of *Voacanga africana* in 1993 alone. Cameroon also exports *Tabernanthe iboga* and *Myrianthus arboreus* but in small quantities (Cunningham and Mbenkum, 1993).

Capsules containing the extract of *P. africana* bark are marketed in Europe where the market value of this trade is estimated at US$ 150 million a year. In addition to Cameroon, Kenya (1,923 tons/year), Uganda (193 tons/year), Zaire (300 tons/year) and Madagascar (78 - 800 tons/year) export this bark to various pharmaceutical companies in Europe mainly to 'Madaus' in Germany and Spain; 'Laboratoires Debat' in France; 'Prosynthese' in France; 'Inverni Della Beffa' and 'Indena Spa' in Italy (Cunningham and Mbenkum, 1993).

Three plants out of the 24,000 indigenous species of the Republic of South Africa have been developed as export products. These are Rooibos tea (*Asplathusa linearis*) 'Marula' (*Sclerocarya birrea*) and *Aloe ferox*. About 500 million South African Rands per annum of traditional remedies are used in the Republic of South Africa (Anati, 1993).

Namibia exports 200 tons of *Harpagophytum procumbens* and *H. zeyheri* tubers annually to Germany (80.4%); France (12.8%); Italy (1.9%); USA (1.5%); Belgium (1%) and South Africa (1.2%) (Cunnigham *et al*., 1992). Unfortunately, the low prices paid for the plants do not cover replacement or resource management costs and as such, major importers demanding high volumes of plant material are contributing to the decline of medicinal plants species in Africa (Cunningham, 1993, Cunnigham *et al*., 1992).

In Madagascar the export sale of *Catharanus roseus* and other plants represent a major export earning for the country. As at 1977, Zambians were spending up to US$28 million a year on traditional medicine (Twumasi, 1994).

Uganda exports the following medicinal and aromatic plants and earned foreign currency on each in 1993 alone as indicated: *Zingiber officinale* (290 Tons; US$130,000); Chilis (333Tons; US$350,000); Soya (7076 Tons; US$2,056,000);

Vanilla (4731Kg; US$328.000); Coffee (114169 Tons; US$106.775.000). Some of the plants exported include *Capsicum frutescens* and *sesamum indicum*.

The roots of *Swartzia madagascariensis* and *Entada africana* are traded 500-800 kilometres from Burkina Faso and Mali to Abidjan in Cote d'Ivoire. Similarly, most of the common chewing sticks are sold across the borders of neighbouring countries in West Africa. Malawi imports plants as finished products from Zimbabwe and South Africa while it exports spices such as chilis to Europe (Gundidza, 1995). 75-80 tons of *Griffonia simplicifolia* seeds are exported each year to Germany from Ghana; commercial gatherers in Cote d'Ivoire chop down *Griffonia simplicifolia* vines, *Voacanga africana* and *Voacanga thouarsii* trees in order to obtain the fruits for export (Cunningham, 1993 a & b). Large quantities of various medicinal plants are also exported to France by SETEXFARM in Senegal. These plants are collected from the wild and there is no evidence of any replanting going on. The amount of replanting of *P. africana* in Equatorial Guinea and Cameroon is not enough. Table 2 shows African medicinal plants that should be cultivated urgently because their demand exceeds supply. Information on the key species marketed is now being updated through a project called TRAFFIC covering East and Southern Africa for a start (Marshall, 1996).

Office National de Developpment des Forets (ONADEF) in Cameroon has applied it's experience of indigenous (e.g. *Terminalia superba*) and exotic timber to species with medicinal values. Three species cultivated for bark production (*Prunus africana* and two exotic *Cinchona* species) and *Voacanga africana* cultivated for it's seed have been propagated in large scale. The foresight of ONADEF in implementing medicinal tree cultivation in plantations and through enrichment planting is exceptional in Africa and is encouraging (Cunningham & Mbenkum, 1993).

The emergence of commercial medicinal plant gatherers in response to urban demand for medicines, rural employment coupled with the export trade has resulted in indigenous medicinal plants becoming an open access or common property resource instead of being a resource only used by the herbalists. The commercial materials largely come from the wild as data from selected African countries affected show little large scale cultivation of plants in those countries. The environmental impact of such harvesting can be very destructive. There is a need for change in the attitude of the international companies requiring these African medicinal plants to one where commercial cultivation and sustainable use of these plants is encouraged. The nationals involved in the export trade on medicinal plants also need to realise the danger posed to this forest resource in their country.

Research on the cultivation of medicinal plants is becoming important because the TMP's are having to travel long distances now before they can get the plants used in that practice. Researchers are also finding it necessary to travel longer distances to get their plants for research especially when it is necessary to scale up the extraction. The attendant problem of picking chemical races when we depend on wild collection for repeat experiments is another reason, beside conservation, for encouraging cultivation of medicinal plants.

PROCESSING OF MEDICINAL PLANTS IN AFRICA

Various (twice or more in some countries) different projects on industrial utilisation of medicinal and aromatic plants have been undertaken by UNIDO in Africa including those to Burkina Faso, Burundi, Cape Verde, Ethiopia, Ghana, Kenya, Madagascar, Mauritius, Niger, Rwanda, Tanzania, Guinea, Senegal Sierra Leone Zambia, Zimbabwe and Nigeria. An export promotion and trade promotion of medicinal and aromatic plant products and essential oils for regional Africa was also organised by UNIDO in 1995. How has Africa faired in the actual industrilisation of its medicinal plant processing? What are the prospects problems, and constraints with respect to industrial utilisation of African medicinal and aromatic plants?

Little large scale processing of the well researched plants and their extracts into standardised dosage forms has taken place despite the amount of formulation studies that has been carried out on them.

Prospects, Problems and Constraints with Respect to industrial Utilisation of African Medicinal Plants

The Status of Drug Production in Africa

Africa as a whole accounts for less than 1% of the world pharmaceutical production. The continent is virtually dependent on the importation of pharmaceuticals in both ready-to-use drugs and bulk drugs for local formulation/production into dosage forms. Indications are that local drug production accounts for only 20% of consumption in most cases. Many of the formulation units not only import drugs, additives and excipients but also the packaging materials and even the labels. Such, unfortunately, is the general state of pharmaceutical industry in the region with few exceptions such as Egypt, Algeria, Ethiopia, Ghana and South Africa.

A survey which I carried out for UNIDO in East Central and Southern Africa (UNIDO, 1991) showed that although several medicinal plants abound and in good quantity in some cases these are not yet exploited commercially in drug production. The utilised capacities of the pharmaceutical industry in each country visited was less than 50%. This could well be the average situation for the continent. Yet, the unutilised capacities can be diverted to the production of simple standardised extracts from medicinal plants for local use and export so as to earn some foreign exchange. Production of simple extracts increases the value added for such plants by ten times compared with exporting them as raw plant materials which some African countries (e.g. Cameroon, Madagascar, Botswana etc.) do at present to earn foreign exchange. In some cases, the high value plant-derived drugs are sold back to Africa. This increases the pressure on the scarce foreign exchange resources of African countries.

About 80 per cent of the population of Africa lives in rural areas and have no access to conventional medicines. They depend on herbs prescribed by traditional healers. The USA has been using herbal drugs up to the tune of 25% on average every year over the last 25 years or more in the prescriptions dispensed in its public pharmacies. A country like Nigeria uses less than 5% of plant derived drugs in its health care. If this is true for other African countries then Africa is under utilising its medicinal plant resources to make drugs. Whereas the US spends over US 8 billion dollars on plant-derived drugs annually, scarce foreign currency in Africa is spent in purchasing synthetic drugs and which are getting more and more expensive.

Future manufacturing of drugs from medicinal plants offer African countries opportunities to develop their pharmaceutical industries with medicinal plants as raw materials in stages as follows:

(a) Presentation of the plant drug as such in standardised crushed or powdered form:
(b) Preparation for crude extracts:
(c) Isolation of active principles or intermediates from the extracts and
(d) Processing of intermediates into active principles.

In order to achieve this in the near future, maximum use needs to be made of existing drug manufacturing facilities in order to optimise the advantages to be derived from local drug production from medicinal plants. Staff can be put on shift work in order to keep the equipment working at full capacity for 24 hours. Regular maintenance will prevent total breakdown of machines and also spot dangers well ahead. Diversification of products to be made is also recommended in order to optimise the use of existing facilities. Plantations of desirable high yielding strains of the medicinal plants to be put on production line should be established in order not to exhaust the wild strains and also to provide enough raw materials to occupy the machines.

The know-how and technology for processing medicinal and aromatic plants already exists and can be transferred through UNIDO. The compilations of various medicinal and aromatic plants that can be produced for local use and export have been made in many African countries and for Africa as a whole by researchers. The African Pharmacopoeia has also published monographs for 100 medicinal plants for which production can start right away since the quality requirements data are there specified. Procedure for ensuring quality of herbal drugs has also been specified by WHO (1991). UNECA (1989) has already examined the chances of recovery of investment in the industrial production of medicinal and aromatic plants in Africa and concluded that investment can be recovered within a year for producing oil of Ginger and within two years for producing oil of cloves, as examples.

The craze for natural medicines or phytomedicines or phytopharmaceuticals and flavours is on the increase and the raw materials to produce them in large scale are abundant in Africa. The increasing cost of modern drugs coupled with the decline in the purchasing power of the African people due to the weakening of the African currencies and the limited national resources with competing demands which are many make it mandatory that efforts should be intensified in Africa to produce drugs from plants since this raw material is abundant in the region's forests.

Many research findings have been published or are published in MS & Ph.D. theses projects in our various libraries. Yet the public is not benefiting from these research findings. Emphasis henceforth should be on how to bring the existing knowledge to the use of the people through the development of simple formulation (Standardized teas, powders, simple extracts etc.) of the effective, safe medicinal plants in a standardized form that will make the medicines still affordable for our people. A database of research findings in the region so far so they can be exploited nationally, at subregional level or at regional level is also necessary for this.

The Constraints and Problems

Despite all the above prospects of processing medicinal and aromatic plants in Africa several countries are not taking advantage of the situation. Some of the constraints mentioned in the countries visited are:

a) **Equipment cost**: Many investors and officials in government believe that the initial outlay on equipment for production is a setback.

b) **Cultivation**: securing sufficient acreage of land to cultivate enough medicinal plants to provide sufficient raw material for the production plant, maintenance of this agricultural complement and funding this aspect has also been considered a limitation.

c) **Lack of research equipment**: The shortage or complete lack of research equipment for R & D work (especially bioassays) to bring up new plants for exploitation have also been advanced by scientists as limitation to getting to the production stage.

d) **Problems of patenting discoveries**: Many researchers fear the loss of their rights to discovery once the plant is put into production. Others complain of inavailability of patent laws. The cost of patenting, lack of expertise in the country to advise on and process patents etc. are among problems faced by interested developers in this area.

e) **Finding markets:** Many people in Africa only know of local markets for their medicinal plant products and are not sufficiently stimulated to scale up production. Information about world markets, current prices as well as demand are not readily available.

f) **Political instability**: The fact that civil unrest and change of government takes place often in Africa has affected progress in the industrialisation of medicinal and aromatic plants in Africa. The cases of Rwanda and Guinea have been cited as examples. The recent civil war in Rwanda has seriously affected personnel and the productivity of the model pilot extraction plant in Butare while the change in the political set up in Guinea has resulted in the closure of the company set up to produce drugs from plants.

g) **The political will**: The will of the government to develop traditional medicine and medicinal plants is paramount. Lack of government policy to develop medicinal plants industrially has been advanced as the reason for inactivity in some countries since the necessary machinery for a quality control agency and for incentives are not put in place by government.

h) **Funding:** Foreign investors need political stability as well as stable government policy to assure returns on their investment. Local investors, prefer to finance well proven or 'safe' areas for their investment. Local investors for example, would rather finance production of aspirin, paracetamol or chloroquine where returns on investment is certain instead of venturing into producing plant extracts for treating sickle cell anaemia or essential oils of clove, for example. Local banks are sceptical of granting loans in this area of development.

i) **Why produce when we can import?** Many bureaucrats prefer to spend government money on importation of plant derived drugs (even powders of plants, extracts and purified plant extracts) since the price offered by the importer is cheaper than cost of production locally. This reason is advanced even by highly placed decision makers in government to whom the following reasons against importation should be clear: importation provides markets and therefore, jobs for the citizens of

the foreign countries. In other words, jobs that could be given to African nationals to reduce the unemployment in Africa are, in effect, given to developed countries. Also, multinationals will subsidise the cost of sale just to keep their factories going abroad; some of the advisers to government in this area are themselves consultants to the multinational companies and would wish to keep their contacts. Such consultants are used to keep the importation of foreign products going so that sales can keep going up; a number of people in the decision making process get kickbacks from the importation exercise. Africa's pharmaceutical industry will not develop if effort is not made to process plants for standardised plant drugs so that improvements can be made to make competition with the world market possible; the people in the rural areas will continue to use herbal remedies in the unstandardised form and in uncontrolled dosage, unless the standardised dosage forms are made available to the masses.

j) **Inadequate production demonstration units in Africa**. The fact that only Rwanda, for a long time, could be quoted to prove to investors and governments that drug production from plants is a viable venture has been advanced as a limiting factor. The failures of the large scale plants for *Cinchona* plantations in Guinea and Cameroon are quoted often as cautionary.

k) **Lack of infrastructure**: Some countries are still battling with rural electrification and water supply. These are considered essentials for a processing plant and the complementary large scale cultivation plantation which will need irrigation.

l) **Bias against traditional medicine by some health personnel**: The decision making authority in some countries is manned by conservative orthodox medical practitioners who will not agree to any development for plant medicines and traditional medicine in general.

Many of these constraints advanced can be solved by UNIDO through its technical assistance programmes to developing nations which supports industrial production and commercialisation of good quality products. Through this programme, some developing Asian countries have increased their exports of volatile oils and isolates as well as producing standardised plant based medicines for local use. In addition, UNIDO supports R & D activities, market studies, trade promotion, total quality management, upgrading of factories and solving problems etc.

m) **Delay in actualising project proposal:** The lengthy evaluation process in UNIDO or UNDP have been advanced by some centres as frustrating their enthusiasm. By the time approval comes for a project the originators of the idea may have been shifted from their point of authority.

Protection of Intellectual Property Rights (Traditional Resource Rights) in Africa

In Africa, although patentable research results have been obtained many of these have not been exploited commercially yet. Two regional organisations in Africa are involved in the management of intellectual property namely, The African Intellectual Property Organisation (OAP) and the African Regional Industrial Property Organisation (ARIPO). Patent legislation is rudimentary and in many cases non-existent in many African countries (Isoun, 1989). Knowledge about intellectual property rights is weak even among the educated elite in Africa (Sofowora, 1996).

There is a need for a mechanism to induce commercialisation of novel findings and processes through the existing expertise in UNECA, UNDP, TCDC and UNIDO which are not sufficiently utilised in this area of medicinal and aromatic plants by African nations. [redacted].

African countries should look critically into the modalities of patenting their leading national biological diversity products and knowledge in order to protect the indigenous scientists, farmers, communities and herbalists from exploitation by people from outside the region. Africa should resolve, through AMCEN not to recognise any form of pirate patenting of African biological diversity or knowledge in cases where there was no prior and informed consent (Okigbo, 1994.). The existing patent laws should be restructured as the case may be.

Areas of Need And Future Collaboration

Areas of future co-operation required will include taxonomy. This is because there is a shortage of taxonomists in Africa to prepare an inventory of our medicinal plant resources; Institutional strengthening will be required for research and development capabilities in medicinal plants right up to processing of the plants at pilot or industrial scale with assistance from UNIDO. It is necessary to undertake national biodiversity inventories and produce periodic national biodiversity assessments in line with the spirit of CBD COP meetings.

The volume of information coming out on biodiversity and intellectual property rights issues are enormous and this is becoming a challenge. The price for not pursuing this challenge is heavy: Without the 'right' information incorrect decisions can be made and scarce resources used unwisely. A thorough assessment of information needs is a critical initial step, therefore. The World Conservation Monitoring Centre (1996) in Nairobi has published a "Guide to Information Management in the Context of the Convention on Biological Diversity". This document focuses on how to make these processes work in practice, ensuring that efforts invested in the information cycle are cost-effective, timely and sustainable.

Recommendations

1. The formation of networks of laboratories to bring African countries together for collaborative research and development work on medicinal plants should be further encouraged in order to maximise the use of facilities for research. More institution and capacity building should be sought through TCDC and other sources.

2. Some countries in Africa (for example, Rwanda, Egypt, Mali etc.) now cultivate medicinal plants on a large scale for local processing into galenicals, teas, various dosage forms and other standardized preparations for use in health care. It is expected that activity in this direction will increase in Africa with assistance from UNIDO since more can be derived economically by making simple extracts of medicinal plants instead of exporting them as raw materials.

3. Tissue and suspension cultures of some African medicinal plants have been developed both for conservation and as a drug production tool in various laboratories.

Examples include *Catharanthus roseus*, *Ammi majus* and *Ammi visnaga* (Zsoke et al., 1991) and *Tribulus terrestris* (Erhun & Sofowora, 1986). The application of biotechnology to plant drug production and conservation in gene banks will need to be intensified to prepare for the future demands of drugs in relation to conservation efforts.

4. The African nations should set up effective legislative machinery to control the collection and exportation of our biological resources in such a way that will enable us to harness our share of partnerships that will ensue from the joint exploitation of their respective biological resources. This could be achieved by requesting full information about any intended plant collection and any anticipated environmental impact. Two separate legally binding agreements should be made in such cases: one to cover access regulations and the other to establish a benefit sharing plan. A separate permit for exporting plant material should be required. Fiji has set up a bill along these lines and is being well monitored (Aalbersberg, 1996).

5. Inter-African and International co-operation in the area of medicinal plant cultivation (especially for countries that share borders or are in the same ecological zones as is done by Mali and Burkina Faso), processing and conservation is also important. The ethnobotanical surveys need to be intensified and carried out with the assistance of international organisations so that we can document available medicinal plants in our countries while noting the ones that are becoming rare. There is a need for capacity building for this by training taxonomists. Other areas that require capacity building and sharing of information even with other developing countries of the world through TCDC include storage and marketing so that profits can be maximised where exportation of medicinal plants can be done in a sustainable way.

6. The procedure for recognising and remunerating intellectual property rights of villagers should involve some knowledgeable people to ensure that adequate remuneration is provided for the traditional resource rights/intellectual property rights of the village community. The procedure should include in addition to capacity building other forms of emolument such as that the country of origin of a promising lead in drug development when patented should be given up-front payments from expected royalties

7. The present focus on the tropical rain forest, for all its merits, should not make us ignore the possibilities that abound in the other biomes in our region or country. In particular, the arid and semi-arid zones have some biodiversity peculiar to those zones. Similarly, the population's dependence on wild local plants is substantial in the sahel region. In many cases the people do not see food and medicine as distinct exclusive categories. For example, people in Gourma, Northern Mali, depend upon the natural vegetation, both indirectly as pasture for their livestock, and directly as food. In such situations plants with more specific habitat requirements and which are less frequent are exposed to overuse (Hveem et al., 1996).

8. The example of Egypt, Rwanda and Zimbabwe in production of drugs from medicinal and aromatic plants should be followed for maximising the use of local expertise in drug development as well as local production of pharmaceuticals.

9. There is an urgent need for more large scale cultivation of medicinal plants in Africa in order to improve the situation on the crude drugs trade as well as to take care of conservation of species going into extinction.

10. For the moment effort should be made to educate herb sellers and herbalist so as to enlist them into conservation efforts.

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Table 1

African Medicinal Plants Exported for Their Active Ingredients

SPECIES	PART USED	INGREDIENT	SOURCE AREA
Allanblackia flo -ribunda	fruit	fat	Cote d'Ivoire
Ancistrocladus abbreviatus	plant	Michaelamine A and B (Alk)	Cameroon and Ghana
Corynanthe pach -yceras	bark	yohimbine	G
		corynanthine	
		corynanthidine	G
Dennetia tripetala	fruit	essential oil	G
Griffonia simpli -cifolia	seed	BS11 lectin	G, CI, CA,
Harpagophytum procumbens	root	glucoiridoids	Namibia
H. zeyheri	root	glucoiridoids	Namibia
Hunteria eburnea	bark	eburine etc	G
Jateorhiza palmata	root	palmatine	Tanzania
		jateorhizine	
		colombamine	
Pausinystalia johimbe	bark	yohimbine	Ca
Pentadesma butyracea	fruit	fat	CI
Physostigma venenosum	fruit	physostigmine (eserine)	G CI
Prunus africana	bark	sterols	Ca,
		triterpenes	Kenya,
		n-decosanol	Madagascar
Rauvolfia vomitoria	root	reserpine	Zaire,Rwanda
		yohimbine etc	Mozambique
Strophanthus spp.	fruit	Ouabain	West Africa
Voacanga africana	seed	voacamine	CI, Ca, G
Voacanga thouarsii	seed	voacamine	Ca

Ca= Cameroon; CI= Cote d'Ivoire; G= Ghana.
After Cunningham (1993 a & b).

Table 2.

African Medicinal Plants Whose Demands Excede Supply

Alepidea amatymbica (Apiaceae)
Asclepias cucullata (Asclepiadaceae)
Begonia homonymma (Begoniaceae)
Boweia volubilis (Lilliaceae)
Cassia abbreviata (Fabaceae)
Cassia sp (unidentified species known as muwawani)
Dianthus zeyheri (Illecebraceae)
Garcinia afzellii (Clusiaceae)*
Garcinia mannii (Clusiaceae)*
Howorthia limifolia (Lilliaceae)
Monanthotaxis capea (Annonaceae)
Pimpinella caffra (Apiaceae)
Plectranthus grallatus (Lamiaceae)
Siphonochilus aethiopicus (Zingiberaceae)
Warburgia salutaris (Canellaceae)*

*Trees/shrubs with agro-forestry potential.
Compiled from Cunningham (1993 a & b).

"INDIAN EXPERIENCE OF UTILISATION OF MEDICINAL PLANTS AND TRADITIONAL AYURVEDIC MEDICINE IN NATIONAL HEALTH CARE SYSTEM"

Paper for Presentation in

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"Strategies to Strengthen the Utilisation of Medicinal & Aromatic Plants in the National Health Care System"

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INDIAN EXPERIENCE OF UTILISATION OF MEDICINAL PLANTS AND TRADITIONAL AYURVEDIC SYSTEM IN NATIONAL HEALTH CARE

Medicinal plants continue to be an important therapeutic aid for alleviating ailments of humankind. Search for eternal health and longevity and to seek remedy to relieve pain and discomfort prompted the early man to explore his immediate natural surrounding and tried many plants, animal products and minerals and developed a variety of therapeutic agents. Over millenia that followed the effective agents amongst them were selected by the process of trial, error, empirical reasoning and even by experimentation. These efforts have gone in history by the name discovery of 'medicine'.

In many eastern cultures such as those of India, China and the Arab/Persian world this experience was systematically recorded and incorporated into regular system of medicine that refined and developed and became a part of the Materia Medica of these countries. The ancient civilization of India, China, Greece, Arab and other countries of the world developed their systems of medicine independent of each other but all of them were predominantly plant based. But the theoretical foundation and the insights and indepth understanding on the practice of medicine that we find in Ayurveda is much superior among organized ancient systems of medicine. From history we learn that in the ancient times India was known as a place of rich natural resources, knowledge, wisdom and scholarship. People from other countries of the world as China, Cambodia, Indonesia and Baghdad (Egypt) used to come to the ancient universities of India like Takshila (700 BC) and Nalanda (500 BC) to learn health sciences of India, particularly 'Ayurveda'. It is perhaps the oldest (6000 BC) among the organized traditional medicine. It has gone through several stages of development in its long history. It spread with Vedic, Hindu and the Buddhist cultures land reached as far as Indonesia in the

east and to the west it influenced the ancient Greek who developed a similar form of medicine.

India's per capita annual consumption of drugs of Rs.125 is the lowest in the world mainly because medicinal plants constitute the principal health care resources for the majority of population. The World Health Organisation(WHO) estimated that 80% of the population of developing countries rely on traditional medicines, mostly plant drugs, for their primary health care needs. Also, modern pharmacopoeia still contains at least 25% drugs derived from plants and many others, which are synthetic analogues built on prototype compounds, isolated from plants. Transition from synthetic drugs and microbially produced antibiotics to plant based drugs is rapidly gaining acceptance. Global resurgence in the use of plant based drugs is an opportunity for India to attain self-reliance and boost the export of herbal drugs.

The demand on plant based therapeutics is increasing in both developing and developed countries due to the growing recognition that they are natural products, being non-narcotic, having no side-effects, easily available at affordable prices and sometimes the only source of health care available to the poor. Medicinal plants sector has traditionally occupied an important position in the socio-cultural, spiritual and medicinal arena of rural and tribal lives of India. The global thrust areas for drugs from medicinal plants include disease conditions, whose incidence is increasing and where the modern drugs are either unavailable or unsatisfactory.

In a wider context, there is a growing demand for plant-based medicines, health products, pharmaceuticals, food supplements, cosmetics, etc., in the national and international markets. Conservation and sustainable use of medicinal plants are issues on which immediate focus is required in the context of conserving biodiversity and promoting and maintaining the health of local communities, besides generating

productive employment for the poor with the objective of poverty alleviation in tribal and rural areas.

International market of medicinal plants is over US $ 60 billion per year, which is growing at the rate of 7%. India at present exports herbal material and medicines to the tune of Rs.446.3 crores only which can be raised to Rs.3000 crores by 2005. China and India are two great producers of medicinal plants having more than 40% of global biodiversity. China, besides meeting its domestic requirement is earning US $ 5 billion per year from herbal trade. There is thus an enormous scope for India also to emerge as a major player in the global herbal product based medicines. However, this requires a grand strategic plan, which takes a holistic view of the entire situation to boost the export of Rs.10,000 crores by 2010 and minimising the import.

Medicinal plants are used at the household level in a self-help mode. One and a half million practitioners of Indian Medicine (Ayurveda, Siddha & Unani systems) use medicinal plants in preventive/promotive and curative applications. There are about 4,60,000 registered practitioners of Indian Medicine (Ayuveda, Siddha and Unani systems) using medicinal plants in the codified streams. Further, there are 9000 registered pharmacies of Indian medicine and 851 of homoeopathy and a number of unlicensed small-scale units. Besides meeting national demands, they cater 12% of global herbal trade. Pharmacies are mostly owned by family companies and most of them are secretive in trade and largely unregulated.

At present, 90% collection of medicinal plants is from the wild, generating about40% million mandays employment (part and full) and since 70% of plants collections involve destructive harvesting many plants are endangered or vulnerable or threatened. Currently medicinal plants are collected without paying attention to the stage of maturity. They are stored haphazardly for long period of time under unsuitable

conditions. This results in deterioration in quality. Such materials are not acceptable to importers and standard manufacturing drug units.

Marketing of medicinal plants is inefficient, informal secretive and opportunistic. As a result, the raw material supply situation is shaky, unsustainable and exploitative. This results in depletion of resource base, exploitation of rural people (who are the real stewards of the resource), adulteration and non-availability of quality herbal drugs for domestic consumption as well as for exports.

As the price paid to the gatherers tend to be very low, they often 'mine' the plants, as their main objective is to generate income. A critical factor in wild harvesting is the availability of cheap labour to undertake the very labour intensive work of herbal gathering. Women are the main gatherers and also the users. With the rampant deforestation, women have to cover greater distances for the collection of herbs that once grew almost outside their habitation. As forest habitat disappear and over-harvesting for commercial use reduces the stocks of wild medicinal plant material, there is a corresponding drop in the availability of the plants normally used as the first and last resort for all health care by rural population.

Despite the wealth of resources (biological, human and financial) available, the sector has not fully developed in the absence of suitable standardisation, quality control of drugs. It has yet to formalize and organise marketing and trade and integrate the development of medicinal plants from production to consumption to boost export of herbal formulations.

Medicinal plants sector has a number of stakeholders having divergent interests. Each stakeholder is interested in strengthening specific aspects of his sector only and ignoring the overall development. Unless coordinated efforts are made the sector cannot develop.

Several constraints exist due to inadequate awareness; inadequate investments in research and development; manufacturer – exporter

dissonance; lack of quality and standardization norms; and lack of adequate marketing and trade informations.

It has been recognized that apart from the software industry, the plant based pharmaceutical sector is the only one showing a constant growth of 15% and more. Medicinal plants can be viewed as a possible bridge between sustainable economic development, affordable health care of developing countries.

Traditional Systems of medicine in India functions through two social streams

Folk Medicine Stream

Folk medicine stream comprising mostly the oral traditions practiced by the rural villages. The carriers of these traditions are millions of housewives, thousands of traditional birth attendants, vibe setters, village practitioners skilled in accupressure, eye treatments, treatment of snake bites and the traditional village physicians/herbal healers, the vaidyas' or the tribal physicians. This stream of inherited traditions are together can be categorized as Local Health Traditions(LHT). Local healers are known by different names in different communities e.g., Ozhas, Sourris, Siane etc. LHT represent an autonomous community supported health management system which efficiently and effectively manage the primary health care of the Indian rural mass. LHT is still alive and runs parallel to the state supported organized health care system; but its full potential is still not fully utilized and also that the great service it is rendering to the rural people go largely unnoticed because of the dominant western medicine.

Classical Ayurvedic Stream

At the second level of traditional health care system is the scientific or classical systems of medicine. This comprises of the codified and organized medicinal wisdom with sophisticated theoretical foundations

and philosophical explanations expressed in classical texts like 'Charka Samhita' (1000 BC), 'Sushruta Samhita' (1000 BC), 'Bhela Samhita', and hundreds of other treatises including some in the regional languages covering treaties of all branches of medicine and surgery. Systems like Ayurveda, Siddha, Unani, Amchi and Tibetan, etc. are expressions of the same. Ayurveda was taught in the ancient universities in India and evolved, developed and flourished mostly among the urban centres and thus used to be a refined system of medicine.

Revival of Traditional Medicine

Today we find a renewed interest in traditional medicine. During the past decade there have been an ever increasing demand especially from developed countries for more and more drugs from plant sources. This revival of interest in plant derived drugs is mainly due to the current widespread belief that 'green medicine' is safe and more dependable than the costly synthetic drug many of which have adverse side effects. This resurgence of interest in the plant based drugs have necessitated an increased demand of medicinal plants leading to over-exploitation, unsustainable harvesting and finally to the virtual decimation of several valuable plant species in the wild. Moreover, the habitat degradation due to increased human activities (human settlements, agriculture and other developmental programmes), illegal trade in rare and endangered medicinal plans, and loss of regeneration potential of the degraded forests have further accelerated the current rate of extinction of plants particularly the medicinal plants.

Medicinal Plants Wealth of India

India is rich in medicinal plant diversity. All known types of agroclimatic, ecologic and edaphis conditions are met within India. The biogeographic position of India is so unique that all known types of ecosystems ranging from coldest place like the Nubra Valley with – 57 C, dry cold deserts of Ladakh, temperate and Alpine and subtropical regions of the North-West and trans-Himalayas, rain forests with the world's

highest rainfall in Cheerapunji in Meghalaya, wet evergreen tropicsof Western Ghas, arid and semi-arid conditions of Peninsular India, dry desert conditions of Rajasthan and Gujarat to the tidal mangroves of the Sunderban. India is rich in all the three levels of biodiversity – such as species diversity, genetic diversity and habitat diversity. There are about 426 biomes representing different habitant diversity that gave rise to one of the richest centres in the world for plant genetic resources. The total number of flowering plant species although only 17,000, the intraspecific variability found in them make in one of the highest in the world. Out of 17,000 plants, the classic systems of medicines like Ayurveda, Siddha and Unani make use of only about 2,000 plants in various formulations. The classical traditions were prevalent in the past particularly in the urban elite society. The rural people who constitute 70 to 75% of the Indian populations live kin about 5,76,000 villages located in different agroclimatic conditions. The village people have their own diverse systems of health management. While most of the common ailments were managed in the house by home remedies which included many species and condiments like pepper, ginger, turmeric, coriander, cumins, tamarind, fenagree, tulsi, etc., more complicated cases were attended by the traditional physicians who use a large number of plants from the ambient vegetations and some products of animal or mineral origin to deal with the local diseases and ailments. These are indeed community managed systems independent of official or government system and are generally known as Local Heath Tradition(LHT). The traditional village physicians of India are using about 4500 to 5000 species of plants for medicinal purpose. There is however no systematic, inventory and documentation about the fold remedies of India. There is urgent need to document this fast disappearing precious knowledge system. The oral traditions of the villagers use about 5000 plants for medicinal purposes. India is also inhabited by a large number of tribal communities who also possess a precious and unique knowledge about the use of wild plants for

treating human ailments. A survey conducted by the All India Coordinated Research Project on Ethnobiology(AICRPE) during the last decade recorded over 8000 species of wild plants used by the tribals and other traditional communities in India for treating various health problems. Some interesting observations made in the study is the use of same species found in different regions for the same ailments while some other species are used differentially.

Programmes & Activities on Medicinal Plants in different Departments of the Government of India

1. **Ministry of Health & Family Welfare**

(i) Medicinal Plants Demonstration Gardens (No.80);

(ii) Development of Agro-technique practices(140);

(iii) Establishment of Medicinal Plants Forests(Vanaspati Vans);

(iv) Scheme for Increasing Awareness about the Use of Medicinal Plants;

(v) Setting up of National Medicinal Plants Board;

(vi) Medicinal Plants use in Reproductive Child Health(RCH) Programme;

(vii) Etheno-Medical Survey of Medicinal Plants through the Central Councils for Research in Ayurveda, Siddha & Unani Medicines.

2. **Ministry of Environment & Forests**

(i) Implementation of various Forests acts for conservation, import, export & bio-diversity legislation;

(ii) Botanical Survey of India – Inventerisation;

(iii) In-situ, ex-citu conservation;

  (a) Establishment of bio-sphere reserves (8);

  (b) National parks (87);

  (c) Wild life sanctuaries (447);

  (d) Protected forest areas;

(iv) Etheno-biological studies & documentation;

(v) National afforestation and Eco-development board;

(vi) Scheme for non-timber (including medicinal plant) produce;

(vii) UNDP assisted programme (FRLHT);

(viii) Indian Council of Forest Research (ICFRE);

(ix) State Forest Departments – JFM Programme etc.

3. **Ministry of Science & Technology (Department of Biotechnology)**

(i) Conservation of germplasm;

(a) National Gene Banks for MAP (4);

(b) Micro-propogation;

(c) Genetic improvement;

(ii) Biotechnological Approach for Herbal/Ayurvedic/New Drug Development;

(iii) Pogramme for G-15 & Asian countries.

4. **Ministry of Science & Technology(Council of Scientific & Industrial Research(CSIR)**

(i) Agro-technique development (e.g. CIMAP, RRLs – a Chain of Laboratories including Regional Research Laboratories);

(ii) Phyto-Chemical Drug Discovery/New molecule search;

(iii) Standardisation of Ayurvedic Farmulations;

(iv) Pharmacopoeial Standards Development;

(v) Documentation & Patent related issues.

5. **Ministry of Agriculture**

(i) Indian Council for Agricultural Research – development of agro-techniques (50 MAP);

(ii) Agricultural Universities - Medicinal Plants Demonstration Gardens (16 States) & Agro-technique/cultivation;

(iii) National Bureau of Plant Genetic Resources (NBPGR);

(iv) All India Coordinated Project on Medicinal and Aromatic Plants (NBPGR);

(v) National Horticultural Development Board – scheme of Medicinal Plants.

Indian Ayurvedic Medicines

AYURVEDA

AYU + VEDA (Science of life)

HUMAN BEING: BODY + MIND + INTELLECT + SOUL

CONCEPTS

1. FIVE ELEMENTS: (Panch Mahabhuta)	SPACE (Akash)	AIR (Vayu)	FIRE (Agni)	WATER (Jal)	EARTH (Prithvi)
2. THREE DOSHA (TRIDOSHA)	VATA		PITTA		KAPHA
1. THREE TYPES OF DISEASES :	VATA (Dominating)		PITTA (Dominating)		KAPHA (Dominating)
4. 3 TYPES OF DRUGS:	VATA		PITTA		KAPHA
5. 3 TYPES OF FOOD:	VATA		PITTA		KAPHA

6. DISEASE – IS THE IMBALANCE OF VATA, PITTA & KAPHA.

7. HEALTH - IS A STATE OF BALANCE OF VATA-PITTA-KAPHA.

Ayurveda: Indian Systems of Medicine and Global Growth of Traditional Medicine

The Indian Systems of Medicine (Ayurveda, Siddha, Unani, Yoga & Natutopathy) offer a range of safe, cost effective, preventive and curative therapies which could be very useful inreaching the goal of 'Health for all', in a cost effective manner. In the developed world, the interest in alternative medicine has surged 60% since 1989 and the market is growing at the rate of 15% annually. Employers and insurers including several major Managed Care Organizations have begun to respond to the demand for adding alternative therapies to the insurance coverage. Alternative Medicine practitioners are already working in the U.K., Germany and U.S.A. and the herbal medicines are food supplements are gaining popularity. WHO has estimated that the global market for medicinal herbs and herbal products is today $62 billion and will grow to US $ 5 trillion by 2050. In India, the Central Government Health Scheme already extends reimbursement to Government servants who opt to avail of treatment under the Ayurveda, Siddha, Unani and Homoeopathy systems in recognized centres. However, for quality drugs to be available there has to be an assured supply of medicinal plants. Except for Yoga and Naturopathy which are drugless therapies all the systems need plants for the preparation of medicines.

Infrastructure

There is a huge infrastructure available in India and according to information updated till 1998, there are 2,862 hospitals, 22,104 dispensaries and 5.87 practitioners of Indian medicine and homoeopathy in the country. There are more than 300 colleges, conducting 5 ½ year degree courses and 45 Ayurvedic colleges imparting postgraduate training apart from Gujarat Ayurved University, Jamnagar, Institute of Medical Sciences, Banaras Hindu University and National Institute of Ayurveda,

Jaipur which offer both Postgraduate and Doctoral courses. Postgraduate colleges have been established under the Unani, Siddha and Homoeopathy systems as well. There are 3 autonomous Research Councils and their responsibility includes conducting clinical research into health care, drug research covering survey and cultivation of medicinal plants, pharmacognosy, phyto chemistry, pharmacology, toxicology, drugs standardization, literary research for revival of the ancient classical literature and research into antenatal and postnatal care and the development of contraceptive drugs. The Pharmacopoeia Committees are working rapidly to see that formularies are prepared for all the drugs of common usage under all the systems of medicine. This will help standardize the drugs.

All details about the work being done in the Research Councils, their publications, the outcome of their research work are available on the internet. The Web site numbers are given below:

Central Council for Research in Ayurveda & Siddha (CCRAS) - ccras@del6.vsnl.net.in

Central Council for Research in Unani Medicine(CCRUM) – ccrum@del3.vsnl.net.in

Central Council for Research in Homoeopathy(CCRH): ccrh@del3.vsnl.net.in

Central Council for Research in Yoga & Naturopathy(CCRYN): ccryn@nda.vsnl.net.in.

Infrastructure of Indian Systems of Medicine

1.	Institutionally trained practitioners	-	4.00 lakhs
2.	Number of non-institutionally qualified practitioners	-	2.11 lakhs
3.	Colleges - - -		305
4.	Admission capacity per annum in Indian systems of medicine & homoeopathy colleges	-	14,204

5.	Number of Drug Manufacturing Units	-	9,456
6.	Number of hospitals of Indian systems of medicine & homoeopathy (in Govt. sector)	-	2,854
7.	Number of beds in hospitals of Indian systems of medicine & homoeopathy	-	49,353
8.	Number of dispensaries of Indian systems of medicine & homoeopathy (in Govt. sector)	-	22,735

INDIAN LEGISLATIONS TO REGULATE AYURVEDIC MEDICINE:

1. INDIAN MEDICINE CENTRAL COUNCIL ACT (1970) – ON EDUCATION & REGISTRATION
2. DRUGS & COSMETIC ACT 1940 & RULES MADE THEREUNDER
3. MAGIC REMEDIES (OBJECTIONABLE ADVERTISEMENT) ACT.

STATUTORY BODIES

AYURVEDA, SIDDHA, UNANI DRUGS TECHNICAL ADVISORY BOARD, DRUGS CONSULTATIVE COMMITTEE

Eight Branches/Specialities of Ayurveda

1.	**Internal Medicine**	-	**Kayaschikitsa**
2.	**Pediatrics**	-	**Kaumarbhritya**
3.	**Psychiatry**	-	**Grahachikitsa**
4.	**Opthalmology & E.N.T.**	-	**Shalakyatantra**
5.	**Surgery**	-	**Shalyatantra**
6.	**Toxicology**	-	**Vishatantra**
7.	**Geriatrics**	-	**Rasayanatantra**
8.	**Knowledge of Virilifics**	-	**Vajikarnatantra**

EDUCATION

Affiliated to the Universities: -

1. Graduate B.A.M.S. degree course of 5½ year duration.
2. M.D. (Ayu) Post Graduate degree of 3 year duration. (45 Institutions in India)
3. Ph.D. - Ayurveda Research degree.

Premier Institutions: -

1. Gujrat Ayurved University – Jamnagar
2. Faculty of Ayurveda – Banaras Hindu University.
3. National Institute of Ayurveda – Jaipur.

Directorate of Indian Medicine/Ayurveda: -

18 state Govts. have separate Directorate of Indian System of Medicine – Ayurveda.

Use of Medicinal Plants in Ayurveda in various Pharmaceutical Dosage Form

1. Five forms of raw herbs in simple dosage form:

(i) Swarasa - Fresh juice

(ii) Kalka – Paste

(iii) Kwath – Hot Infusion

(iv) Phanta – Hot Infusion

(v) Him, Sheet Kshya – Cold infusion

2 Asava & Arishta (Fermented liquid with self-generated alcohol);

3 Other alcoholic 8 products are: Sura, Varuni, Sidhu, Shukta, Kanji, Tushodaka, Soubeer, Surassera;

4 Arka (Distilled plant material with volatile oild);

5. Avaleha & Paka (Confections):

   (a) Modak (Bolus)

   (b) Khand (Sugar mixed powder);

6. Kwatha Churna (Coarse Powders for decoction);

7. Ksheera pak – (Decoction in milk);

8. Gharita (Medicated Ghee – Clarified Butter);

9. Churna (Fine powder);

10. Taila (medicated oils);

11. Lavana (Salts derived from plants);

12. Kshara (Salts & Alkali of plant origin);

13. Lepa (Preparation for local application on skin);

14. Vati and Gutika (Tablets & pills);

15. Varti (Suppositories);

16. Netra Vindu (Aschhayotna – Eye drops);

17. Sattva (Dried water extract without boilding) – This is insoluble starchy portion of a drug, which is cool in nature.

18. Ghannasatva (Dried water extract after boiling);

19. Varti - Yonivarti (Vaginal suppository)

    - Phalavarti (Anal suppository);

    - Netravarti (Suppository for eyes);

20. Nasya - (a) Nasal drops; (b) Nasal insufflation;

21. Suchivedha – Injectable;

22. Malham (Malhar) – ointments;

23. Ubatana (body/Face pack-paste);

24. Udvartan (Body powders for rubbing over the body parts);

25. Anjana (Fine powders for eyes);

26. Mandura (Herb powders rubbing over the body);

27. Rasa (Herbo-mineral-Metalic combinations).

28. Dhupan – Medicated Fumigation.

Standards of Quality of Ayurvedic Drugs

Quality control in the case of synthetic drugs is much simpler and easier than in the case of drugs prepared from medicinal plans where multiplicity of active ingredients can create a difficulty in quality assurance. The main difficulty in preparing the standards is that most of these products use whole herbs or parts of plants or their extracts and in some cases even a mixture of number of plants. It is also difficult to identify these plants, as, medicinal plants collected in different seasons from the same place can exhibit marked difference in the content of active constituents. It is challenging to develop suitable standards because the preparation of drug based on medicinal plants is regarded as one active entity in is entirety. It is difficult to measure in quantity and quality the various constituents and heir therapeutic activity. Again, the standardization of such drugs does not end with the identification or assay of active ingredient, rather it embodies total information and controls which are necessary to guarantee constituents of composition. Their standards are influenced by many factors such as age of the plant, the area of origin, harvesting time, method of drying, storage condition, manufacturing process, packing etc. Thus, there are a number of bottlenecks in establishing standards of medicinal plants.

Pharmacopoeial Standards of Ayurvedic Drugs

Government of India has set up Ayurvedic Pharmacopoeia Committees and the Pharmacopoeial Laboratory for Indian Medicines(PLIM) to provide technical back up. So far two volumes containing 158 monographs of Ayurvedic drugs have been published in two volumes. Another 160 monographs are ready for publication very shortly. Government of India has also published two volumes of Ayurvedic Formulary of India containing 635 Ayurvedic formulations.

32 other Laboratories in the country are working on plants, minerals & metalic drugs used in Indian system of medicine to evolve standards.

Good Manufacturing Practices(GMP)

Recently, in June 2000, Government of India has notified Good Manufacturing Practices(GMP) for Ayurvedic, Siddha and Unani medicines. This is an important step to improve the quality and standards of Indian medicines. These GMPs are in line with the WHO guidelines for herbal medicines.

Home Remedies with Common Plants Used in Ayurveda

1. Cough and Cold (Irritation in the Chest & throat, headache etc.)

(i) 1-2 gm. Powder of equal parts of Black Pepper (Kali Mirch); Long Pepper (Pippali) and dry Ginger (Sonth) with Honey, 2-3 times a day.

OR

(i) Paste of one segment of bulb of Garlic (Lasuna), boiled in water with 5-10 gm. of sugar, twice a day.

OR

(ii) 1-2 gm. Powder of fried Turmeric (Haldi), with Honey, thrice a day.

2. Vomitting (White, yellow or green coloured frothy vomitting, drowsiness etc.)

(i) Powder of fried seeds of 1-2 Cardamon (Ilaaichi) with Honey, thrice a day.

OR

(ii) Lemon (Nimbu) juice 5-10 ml. mixed with water and a pinch of salt, 2-3 times day.

OR

(iii) 5 ml. lime juice with sugar at one hour intervals.

3. Abdominal Pain (pain around naval)

(i) Powder of Ajowa Fruits (Ajwain), 1 gm., with luke warm water, 2-3 times, at one hour interval.

OR

(ii) Paste of pinch of Asafoetida (Heeng) with luke warm water to be applied on and around naval area.

4. Diarrhoea (Frequent loose/watery motions)

(i) 1-3 gm. of dried Ginger powder mixed with equal parts of sugar, two times a day.

OR

(ii) 1 gm. powder of fried Cumin (Jeera)/Long Pepper(Pippali), dried Ginger (Sonth) with one cup of butter milk, 3-4 times a day.

OR

(iii) 5 gm. Isabgol husk with a cup of curd, twice a day.

5. Constipation (Retention of faeces and gases, discomfort in abdomen)

(i) 5 gm. of fruit rind of Chebulic myrobalan (Harad) with salt,once daily at bed time.

OR

(ii) 2-6 gm. of Triphala powder with 50 ml. warm water, twice a day.

OR

(iii) 5-10 gm. of Isabgol husk with one cup of milk at bed time.

6. Cough (Dry frequent cough, pain in chest, headache, hoarseness of voice etc.)

(i) 2-3 Cloves (laung) fried in ghee be placed in mouth and chewed.

OR

(ii) ½ gm. powder of Long Pepper (Pippali) mixed with rock salt twice daily, with hot water.

OR

(iii) Powder of equal parts of Long Pepper (Pippali) and dry Ginger(Sonth) 5 gm. with Honey, twice daily.

OR

(iv) 5 gm. powder of equal parts of Black Pepper (Kali Mirch) dry Ginger (Sonth) and sugar mixed with butter/ghee, twice daily.

7. Toothache (Pain in tooth)

(i) Cotton soaked in Clove (Laung) oil, be placed near painful teeth.

OR

(ii) Place Asafoetida (Heeng) and salt near painful teeth.

OR

(iii) Put Black Pepper/Clove/Ajowa Fruits (Ajwain) in mouth.

8. Earache (Pain in ear)

(i) Instill warm juice of Ginger (Adrak), 2-4 drops, twice a day.

OR

(ii) Instill warm juice of Radish (Mooli) 2-4 drops, twice a day.

(iii) Instill 2-4 drops of warm juice of Garlic (Lasuna) in the ear, twice a day.

9. Common Colds with Fever (low temperature, feeling of warmth, Pain in body and loss of perspiration)

(i) Decoctionof 2-3 gm. powder of Ginger (Adrak), Black Pepper (Kali Mirch), Long Pepper (Pippali), Liquorice (Mulethi) in equal quantity and 7 leaves of Tulsi 2-3 times a day.

OR

(ii) Decoction of 30 gm. Coriander Fruits (Dhanya) in 100 ml. of water and sugar, once a day in the morning.

OR

(iii) 1 gm. powder of Long Pepper (Pippali) with 5-10 gm. honey, three times a day.

10. Low backache/Joint Pains (Pain in joints and waist region)

(i) Boil 5 gm. dry Ginger (Sonth) in 50 ml. of water and reduce to 20 ml., mix with 5-10 ml. of Castor (Arand) oil, thrice daily.

OR

(ii) 10-20 ml. of Castor (Arand) oil with warm water/milk at bed time.

OR

(iii) Fried Fenugreek (Methi) seeds 1 tablespoon with milk, twice daily.

Common Plants/Parts used in Ayurvedic Home Remedies

	Indian Name		Botanical Name
1.	Kalimirch	-	Piper nigrum Linn
2.	Pippali	-	Piper longum Linn
3.	Illachi	-	Elettaria Cardamomum Maton
4.	Heeng	-	Ferula marthex Boiss
5.	Jaiphal	-	Myristca fragrans Houtt
6.	Pomegranate	-	Punica granatum Linn
7.	Isabgol	-	Plantago oveta
8.	Hard	-	Terminalia chebula Retz
9.	Lavang	-	Syzygium aromaticum Linn
10.	Lasuna	-	Allium sativum Linn
11.	Methi	-	Trigonella foenum-graecum Linn

12.	Ajwain	-	Trachysperumum ammi Linn
13.	Adrak	-	Zingiber officinale Roseoe
14.	Jeera	-	Cuminum Cyminum Linn
15.	Illachi bari	-	Amomum Susulatim Roxb

Common Plants/Parts used in Unani Home Remedies

	Indian Name		Botanical Name
1.	Gulab	-	Rosa centifolia Linn
2.	Mooli	-	Raphanus sativus Linn
3.	Haldi	-	Curcuma longa Linn
4.	Laung	-	Syzygium aromaticum Linn
5.	Reetha	-	Sapindus mukorossi Gaertn
6.	Zeera	-	Cuminum cyminum Lin
7.	Ajwain	-	Trachyspermum ammi Linn
8.	Lamon	-	Citrus lemon Linn
9.	Mulethi	-	Trigonella foenum – graccum Linn
10.	Piyaz	-	Allium cipa Linn
11.	Sonf	-	Foeniculum vulgare Nill
12.	Anar	-	Punica granatum Linn
13.	Kalimirch	-	Pipeer nigurm Linn
14.	Tulsi	-	Occimum sanctum Linn.

Medicinal Plants used in Indian/Ayurveda Medicine

Sl .No.	**Botanical name**
Acting on central nervous system	
1.	Centella asiatica (Linn)
2.	Bacopa minnieri (Linn.)
3.	Convolvulus pluricaulis (Choiy)
4.	Celastrus paniculatus Willd)
5.	Benincasa hispida (Thunb.)
6.	Lavandula stoechas (Linn.)
7.	Papaver somnifrum (Linn.)
8.	Cannabis sativa (Linn.)
9.	Acorus calamus (Linn.)
10.	Nordostachys jatamansi DG
11.	Angelica glauca Edgew
12.	Rauwolfia serpentina Benth ex. Kurz.
13.	Pluchea lanceolata C.B.Clarke
14.	Anthocephalus indicus Miq.
15.	Prunus cerasoides D. Don.
16.	Salix caprea Linn.
17.	Salix terrasperma Roxb.
18.	Atropa belladonna Linn.
19.	Hyoscyamus niger Linn.
20.	Commiphora mukul (Hook. Ex Stocks)
21.	Ricinus communis Linn.
22.	Paederia foetida Linn.
23.	Valeriana wallichii DG.
24.	Vitex negundo Linn.
25.	Allium cepa Linn.
26.	Allium sativum (Linn.)
27.	Cedrus deodara (Roxb.)
28.	Litsea glutinosa (Lour.)
29.	Pterospermum acerifolium (Willd.)
30.	Dalbergia lanceolaria Linn.
31.	Strychnos nuxvomica Linn.
32.	Peonia emodi Wall
33.	Betula utilis D. Don.
Acting on sense organs	
34.	Coptis teeta wall.
35.	Thalictrum foliolosum DG.)
36.	Cassia absus Linn.
37.	Strychnos potatorum Linn.

38.	Crinum latifolium Linn.
39.	Erythrina variegata Linn.
40.	Centipeda minima Linn.
41.	Gymnema sylvestre R. Br.
Acting on sweat glands	
42.	Aconitum ferox Wall ex Sringe
43.	Moringa oleifera Lam.
44.	Vetiveria zizanioidis Linn.
Acting on hair	
45.	Cocos nucifera Linn.
46.	Sesamum indicum Linn.
47.	Eclipta alba Hassk.
48.	Indigofera tinctoria Linn.
Acting on skin	
49.	Brassica juncea Czern & Coss
50.	Gynandropsis gynandra Linn.
51.	Vitis vinifera Linn.
52.	Cordia dichotoma Forst. F.
53.	Crocus sativus Linn.
54.	Pandanus odorotissimus Linn.f.
55.	Pongamia pinnata Pierre
56.	Schleichera oleosa (Lour) oken
57.	Azadirachta indica (A. Juss)
58.	Brassica campestris Linn. Var. Sarson Prain
59.	Sesbania sesban Merrill
60.	Centratherum anthelminticum Kuntze
61.	Acacia catehu Willd
62.	Curcuma longa Linn.
63.	Semecarpus anacardium
64.	Cassia fistula Linn.
65.	Hydnocarpus laurifolia (Dennst.) Sleumer
66.	Psoralia corylifolia Linn.
67.	Jasminum officinale Linn. Forma. grandiflorum Linn.
68.	Lawsonia inermis Linn.
69.	Ficus hispida Linn. F.
70.	Barleria prionitis Linn.
71.	Cassia tora Linn.
72.	Rhinacanthus Nsuta Kurz
73.	Diospyros peregrina (Gaertn) Gurke
74.	Buchanania kabzab Spreng
Third Chapter **Acting on cardio-vascular system**	
75.	Terminalia arjuna (Roxb.)
76.	Cinnamomum camphora Nees & Eberm
77.	Digitalis urpurea Linn.

78.	Urginea indica Kunth
79.	Piper betle Linn.
80.	Nerium indicum Mill
81.	Rosa centifolia Linn.
82.	Coffea arabica Linn.
83.	Elaeocarpus ganitrus Roxb.
84.	Premna mucronata Roxb.
85.	Stereospermum suavelens
86.	Gmelina arborea Linn.
87.	Alocasia indica (Roxb.)
88.	Capparis sepiaria Linn.
89.	Trichodesma indicum R. Br.)
90.	Streblus asper Lour
Acting on Thyroid gland	
91.	Bauhinia variegata Linn.
92.	Ranunculus sceleratus Linn.
Acting on Respiratory System	
93.	Terminalia bellerica Roxb.
94.	Adhatoda vasica Nees
95.	Abies webbiana Lindle
96.	Syzygium aromaticum (Linn) Merr.& Per.
97.	Cinnamomum zeylanicum Breyn
98.	Glycyrrhiza glabra Linn
99.	Onosma bracteatum Wall
100.	Pistacia lentiscus Linn
101.	Commiphora myrrha (Nees) Engl
102.	Dorema ammoniacum D. Don
103.	Styrax benoin Draand
104.	Liquidamber orientalis Miller
105.	Viola odorata Linn
106.	Sisymbrium irio Linn
107.	Lepidium iberis Linn
108.	Althaea officinalis Linn
109.	Hyssopus officinalis Linn
110.	Piper longum Linn
111.	Solanum surattense Burm.f.
112.	Solanum indicum Linn
113.	Pistacia integerrima Stewart ex Brandis
114.	Cassia occidentalis Linn
115.	Sesbania grandiflora Peres
116.	Hedychium spicatum Buch Ham
117.	Curcuma zedoria Rosc.

118.	Inula racemosa Hook.f.
119.	Clerodendrum serratum (Linn) Moon
120.	Euphorbia thymifolia Linn
121.	Ephedra gerardiana Wall
122.	Alpinia galanga Willd
123.	Adiantum lunulatum Burm
124.	Pinus roxburghii Sargent
125.	Eucalyptus globullus Labill
Acting on Gastro-intestinal system	
126.	Capsicum annurm Linn
127.	Alhagi camelorum Fisch
128.	Fagonia cretica Linn
129.	Fumaria vaillantii Loisel
130.	Coriandrum sativum Linn
131.	Hibicus abelmoschus Linn
132.	Zanthoxylun armatum DC.
133.	Mimusops elengi Linn
134.	Zingiber officinale Rosc.
135.	Piper retrofractum Vahl.
136.	Garcinia indica Chois
137.	Garcinia pedunculata Roxb.
138.	Punica granatum Linn
139.	Citrus medica Linn
140.	Citrus limon (Linn) Burm.f.
141.	Oxalis corniculata Linn
142.	Rhus parviflora Roxb.
143.	Ferula narthex Boiss
144.	Acoitum heterophylum Wall
145.	Coscinium fenestratum Colebr.
146.	Plumbago zeylanica Linn
147.	Piper nigrum Linn
148.	Cuminum cyminum Linn
149.	Carum bulbocastanum W.Koch
150.	Cyperus rotundus Linn
151.	Carica papaya Linn
152.	Randia spinosa Poir
153.	Lagenaria siceraria (Mol.) Standl.
154.	Luffa cylindrica (Linn) M.J. Roem.
155.	Luffa acutangula (Linn) Roxb.
156.	Sapindus trifoliatus (Linn)
157.	Nicotiana tabacum Linn
158.	Barringtonia acutangula Gaertn.
159.	Rotalaria verrucosa Linn
160.	Phaseoolus mungo Linn
161.	Mentha spicata Linn Emend Nethh.

162.	Mojorana hortensis Moench.
163.	Artemisia vulgaris Linn.
164.	Foeniculum vulgare Mill.
165.	Anethum sowa Kurz.
166.	Gardenia gummifera Linn.f.
167.	Artocarpus intera (Thunb Merrill.)
168.	Artocarpus lakoocha Roxb.
169.	Ficus carica Linn.
170.	Linum usitatissimum Linn.
171.	Plantago ovata Forsk.
172.	Cassia angustifolia Vahl.
173.	Operculina turpethum (Linn)
174.	Ipomoea nil (Linn)
175.	Argemone mexicana Linn.
176.	Baliospermum montanum Muell-Arg.
177.	Croton tiglium Linn.
178.	Euphorbia neriifolia Linn.
179.	Catotropis procera (Ait) R. Br.
180.	Cirullus colocynthis Schrad.
181.	Garcinia morella Desr.
182.	Picrorhiza kurroa Royle ex Benth
183.	Rheum emodi Wall.
184.	Aloe vera Tourn ex Linn.
185.	Salvadora persica Linn.
186.	Luffa echinata Roxb.
187.	Aegle marmelos Corr.
188.	Myristica fragrans Houtt.
189.	Coleus amboinicus Lour.
190.	Holarrhena antidysenterica Linn.
191.	Ailanthus excelsa Roxb.
192.	Oroxylum indicum Vent.
193.	Woodfordia fruitcosa Kurz.
194.	Acacia arabica Willd.
195.	Cassia auriculata Linn.
196.	Grewia tiliaefolia Vahl.
197.	Helicteres isora Linn. Prosopis cineraria Druce.
198.	Quercus infectoria Oliv.
199.	Adiantum caudatum Linn.
200.	Cassytha filiformis Linn.
201.	Boswellia serrata Roxb.
202.	Salmalia malabarica Schott & Endl.
203.	Trachyspermum ammi Linn.
204.	Carum roxburghianum (DG) Craib.
205.	Lepidim sativum Linn.

206.	Datura metel Linn.
Anthelmintics	
207.	Embelia ribes Burm. F.
208.	Butea monosperma (Lam.) Kuntze
209.	Artemisia maritima Linn.
210.	Balanites aegyptiaca (Linn.) Delile
211.	Ocimum sanctum Linn.
212.	Ocimum basilicum Linn.
213.	Artemisia absinthium Linn.
214.	Aristolochia bracteata Retx.
215.	Mallotus philippinensis
216.	Clerodendrum infortunatum Linn.
217.	Merremia emarginata (Burm. F.) Hallier f. syn. Ipomoea reniformis Choisy.
Sixth Chapter **Acting on piles, liver and spleen.**	
218.	Melia azedarach Linn.
219.	Capparis decidua Edgew.
220.	Amorphophallus campanulatus Blume.
221.	Marsilea minuta Linn.
222.	Berberis aristata DG
223.	Solanum nigrum Linn.
224.	Achyranthes aspera Linn.
225.	Andrographis paniculata Nees.
226.	Taraxacum officinale Weber ex Wiggers
227.	Cichorium intybus Linn.
228.	Nyctanthes arbor-tristis Linn.
229.	Tecoma undulata G. Don.
230.	Tephrosia purpurea Pers.
231.	Tamarix troupii Hole
Seventh Chapter **Acting on male reproductive system**	
232.	Asparagus adscendens Roxb.
233.	Curculigo orchioides Gaertn.
234.	Asparagus racemosus Willd Euryale ferox Salisb
235.	Asteracantha longifolia
236.	Orchis latifolia Linn.
237.	Mucuna prurita Hook.
238.	Blepharis edulis Pers.
239.	Saussurea lappa C. B. Clarake
240.	Myrica esculenta Buch-Ham.
241.	Anacyclus pyrethrum DG.
Acting on female reproductive system	
242.	Cynodon dactylon Pers.

243.	Nelumbo nucifera Gaetun.
244.	Nymphaea nouchali Burm. f.
245.	Scirpus grossus Linn. f.
246.	Trapa natans Linn. Var. bispinosa (Roxb.) Makino
247.	Putranjiva roxburghii Wall.
248.	Hibiscus rosa-sinensis Linn.
249.	Aristolochia indica Linn.
250.	Nigella sativa Linn.
251.	Claviceps purpuea fr. Tul.
252.	Gossypium herbaceum Linn.
253.	Gloriosa superba Linn.
254.	Costus speciosus (Koeing) Sm.
255.	Paeganum harmala Linn.
256.	Ruta graveolens Linn.
257.	Abroma augusta Linn.f.
258.	Bambusa arundinacea Willd.
259.	Crotalaria juncea Linn.
260.	Symplocos racemosa Roxb.
261.	Saraca asoca (Roxb.) De Wilde
262.	Caesalpinia sappan Linn.
263.	Arundo donax Linn.
264.	Cymbopogon martini (Roxb.) Wats
265.	Jasminum sambac Linn.
266.	Cissampelos pareira Linn.
Eighth Chapter **Acting on urinary system**	
267.	Boerhavia diffusa Linn.
268.	Tribulus terrestris Linn.
269.	Desmostachya bipinnata Stapf.
270.	Saccharum spontaneum Linn.
271.	Saccharum munja Roxb.
272.	Saccharum officinarum Linn.
273.	Phyllanthus urinaria Linn.
274.	Piper cubeba Linn.f.
275.	Juniperus communis Linn.
276.	Ananas comosus (Linn.) Merr.
277.	Dendrophthoe falcata (Linn.f.)
278.	Cucumis sativus Linn.
279.	Bergenia ligulata (Wall.) Engl.
280.	Crataeva nurvala Buch-Ham.
281.	Dolichos biflorus Linn.
282.	Dichrostachys cineria W. & A.
283.	Aerva lanata Juss

(ii) Mutrsangrniy	
284.	Syzygium cumini (Linn.) Skeels.
285.	Mangifera indica Linn.
286.	Ficus bengalensis Linn.
287.	Ficus glomerata Roxb.
288.	Ficus religiosa Linn.
289.	Ficus lacor Buch-Ham.
290.	Shorea robusta Gaertn.
291.	Vateria indica Linn.
292.	Anogeissus latifolia Wall.
293.	Ougenia oojeinensis (Roxb.) Hochr.
294.	Ficus rumphii Blume
295.	Flacourtia ramontchi L. Herit
296.	Thespesia populnea Soland ex Correa
Antidiabetics	
297.	Pterocarpus marsupium Roxb.
298.	Momordia charantia Linn.
299.	Salacia chinensis Linn.
300.	Coccinia indica W. & A.
Ninth Chapter **Antipuretics**	
301.	Vernonia cineria Less
302.	Swertia chiraita (Roxb. Ex Flem.)
303.	Adina cordifolia Benth & Hook.f.
304.	Gentiana kurroo Royle
305.	Trichosanthes dioica Roxb.
306.	Marsdenia tenacissima W. & A.
307.	Polyalthia longifolia Thw.
308.	Alstonia scholaris R. Br.
309.	Enicostemma littorale Blume
310.	Caesalpinia crista Linn.
311.	Leuscas cephalotes Spreng
312.	Ocimum sanctum Linn.
313.	Cinchona officinalis Linn.
314.	Nymphaea stellata Willd.
Acting on sensory nervous system	
315.	Santalum album Linn.
316.	Pterocarpus santalinus Linn.
317.	Elettaria cardamomum Maton
318.	Michelia champaca Linn.
Effective in gangrene wound healing	
319.	Ceratophyllum demersum Linn.

320.	Parmelia perlata Ach.
Strength promoters/Tonics and Rejuvenators	
321.	Aquilaria agallocha Roxb. .
322.	Amomum subulatum Roxb.
323.	Lodoicea maldivica (Poir.) Pers
324.	Dipterocarpus turbinatus Gaertn.
325.	Grewia tenax (Forsk.) Aschers. & Schwf
326.	Sida cordifolia Linn.
327.	Abutilon indicum (Linn. Sw.)
328.	Sida rhombifolia Linn. Mast.
329.	Sida veronicaefolia Linn.
330.	Pueraria tuberosa DC
331.	Dioscorea bulbifera Linn.
332.	Curcuma angustifolia Roxb.
333.	Ledtadenia reticulata W. & A.
334.	Phaseolus trilobus Ait.
335.	Teramnus labialis Spreng.
336.	Mimosa pudica Linn.
337.	Areca catechu Linn.
338.	Terminalia chebula Retz.
339.	Emblica officinalis Gaertn.
340.	Tinospora cordifolia (Willd) Miers ex Hook.f. & Thoms.
341.	Withania somnifra (Linn.) Dunal
342.	Argyreia speciosa Sweet.
343.	Grewia hirsuta Vahl.
344.	Sansevieria roxburghianum Schult.f.
Effective in toxaemia, toxic reactions	
345.	Albizzia lebbeck Benth.
346.	Delphinium denudatum Wall.
347.	Cocculus hirsutus (Linn.) Diels
348.	Alangium salvifolium (Linn.f.) Wang
349.	Callicarpa macrophylla Vahl.
Haemostatics and blood purifiers	
350.	Mesua ferrea Linn.
351.	Mammea longifolia planch. & Triana.
352.	Colopphyllum inophyllum Linn.
353.	Bryophyllum pinnatum (Lam.) Kurz.
354.	Eupatorium triplinerve (Vahl.)
355.	Tagetes erecta Linn.
356.	Tectona grandis Linn.f.
357.	Daemenorops draco Blume.
358.	Blumea lacera DC.
359.	Pistia stratiotes Linn.
360.	Hemidesmus indicus R. Br.
361.	Rubia cordifolia Linn.

362.	Smilax china Linn.
363.	Dalbergia sissoo Roxb.
364.	Colchicum luteum Baker
Body weight enhancers	
365.	Phoenix sylvestris Roxb.
366.	Madhuca indica J. F. Gmel.
367.	Agaricus campestris Linn.
Anti-obesity	
368.	Holoptelea integrifolia
Antistiffness/or useful in general bodyache	
369.	Iris ensata Thunb.
370.	Desmodium gangeticum DC.
371.	Uraria picta Desv.
Wound healer	
372.	Trigonella foenum-graecum Linn.
373.	Soymida febrifuga A. Juss
Bone healers or fracture healers	
374.	Cissus quadrangularis Linn.
Useful in muscle wasting	
375.	Capparis monii Wight.
376.	Caesalpinia digyna Rottl.
Useful in leukemia	
377.	Lochnera rosea (Linn.) Reichb.
378.	Podophyllum hexandrum Royle

"INDIAN EXPERIENCE OF UTILISATION OF MEDICINAL PLANTS AND TRADITIONAL AYURVEDIC MEDICINE IN NATIONAL HEALTH CARE SYSTEM"

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GLOBAL SCENARIO OF ALTERNATE MEDICINE MARKET

- According to the Report prepared by Mc Alpine Thorpe and Warrier limited, U.K. for Common Wealth Secretariat the global herbal market is estimated to be Rs. 51,000 crores. Out of this, Indian export is only Rs. 280 crores which is 0.5% of total export market while share of China exports is Rs. 18,000/- crores which is 35.3% of total market.

- According to the WHO the global market for medicinal herbs and herbal products is estimated to touch US$ 5 trillion by 2050.

CONT.

GLOBAL SCENARIO OF ALTERNATE MEDICINE MARKET

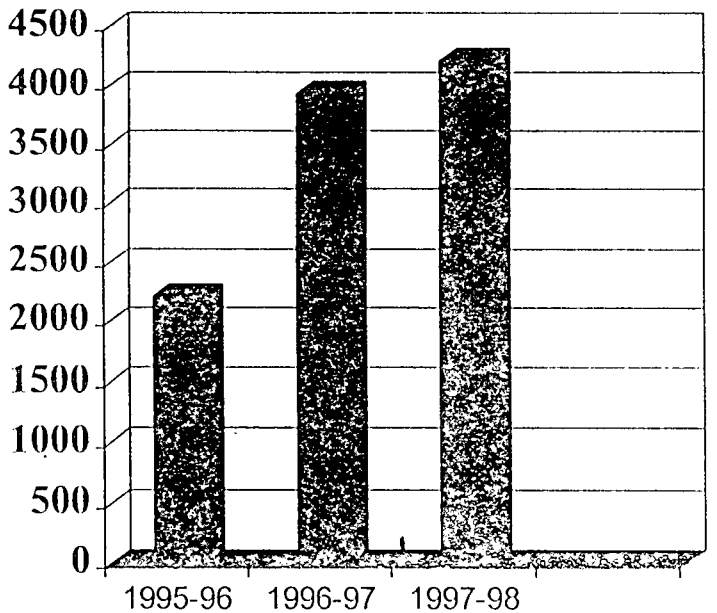
- In Germany, there are 10000 - 13000 alternative medicine practitioners and 75% of the physicians use complementary medicine.
- In the United Kingdom, 90% of the population use complimentary medicine and there are 8000 non-allopathic practitioners.
- In United States, a National Follow-up Survey has shown that use of alternative therapies have increased from 30% to 42% and the growth proportion is expected to increase to 60%.

GLOBAL SCENARIO OF ALTERNATE MEDICINE MARKET

- WHO have reported that in 1998, 60% of the Australian population used alternative medicine and 17000 herbal products accounting to one billion Australian Dollars have been registered.
- In Belgium, according to a 1998 poll survey almost 40% of the population have used complementary medicine and 59% of the doctors are also using this and in particular Homoeopathy medicines in which we have a strength.
- In France, 49% of the people have used complementary medicine and Homoeopathy and herbal medicine are particularly popular.

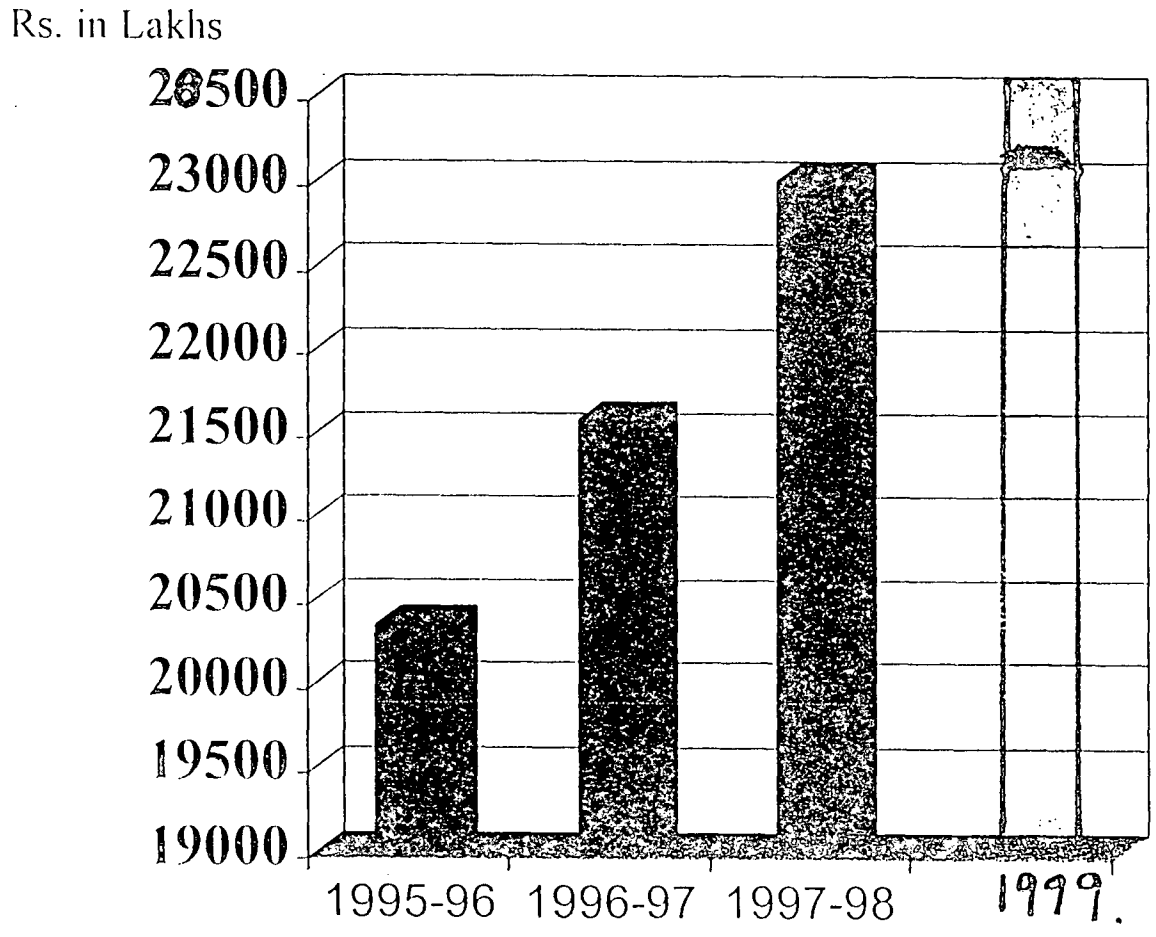
EXPORT OF AYURVEDIC & UNANI MEDICINES FOR THERAPEUTIC USE NOT FOR RETAIL SALE

Rs. in Lakhs



Monthly Statistics of the Foreign Trade of India, March 1996, March 1997 and March 1998 (Annual Numbers for 1995-96,1996-97 and 1997-98)

EXPORT OF PLANTS AND PARTS OF PLANTS



Monthly Statistics of the Foreign Trade of India, March 1996, March 1997 and March 1998 (Annual Numbers for 1995-96, 1996-97 and 1997-98)— 1999.

MEDICINAL PLANT SECTOR'S PROBLEMS

(g) Unsustainable wild harvesting.

(h) Lack of organized Trade.

(i) Lack of authentic demand supply data.

(j) Lack of coordination amongst stake holders viz. Ministry of Agriculture, Ministry of Environment and Forests, Ministry of Commerce, Department of ISM&H, Department of Science & Technology, State Governments, Drug Controller, private / traditional medicine sectors, international players etc.

MEDICINAL PLANT SECTOR'S PROBLEMS

The Indian Medicinal Plants Sector is affected by a number of limitations such as :

(a) Lack of consistent quality raw material.

(b) Lack of assured availability.

(c) Lack of national policy on medicinal plants conservation.

(d) No eco-mapping done so far.

(e) Lack of agro-techniques.

(f) Lack of organised market system.

CONT.

1.Ministry of Health & Family Welfare

(viii) Medicinal Plants Demonstration Gardens (No.80);

(ix) Development of Agro-technique practices(140);

(x) Establishment of Medicinal Plants Forests(Vanaspati Vans);

(xi) Scheme for Increasing Awareness about the Use of Medicinal Plants;

(xii) Setting up of National Medicinal Plants Board;

(xiii) Medicinal Plants use in Reproductive Child Health(RCH) Programme;

(xiv) Etheno-Medical Survey of Medicinal Plants through the Central Councils for Research in Ayurveda, Siddha & Unani Medicines.

2. **Ministry of Environment & Forests**

(i) Implementation of various Forests acts for conservation, import, export & bio-diversity legislation;

(ii) Botanical Survey of India – Inventerisation;

(iii) In-situ, ex-citu conservation;

(e) Establishment of bio-sphere reserves (8);

(f) National parks (87);

(g) Wild life sanctuaries (447);

(h) Protected forest areas;

(iv) Etheno-biological studies & documentation;

(v) National afforestation and Eco-development board;

(vi) Scheme for non-timber (including medicinal plant) produce;

(vii) UNDP assisted programme (FRLHT);

(viii) Indian Council of Forest Research (ICFRE);

(ix) State Forest Departments – JFM Programme etc.

4. **Ministry of Science & Technology(Council of Scientific & Industrial Research(CSIR)**

* Agro-technique development (e.g. CIMAP, RRLs – a Chain of Laboratories including Regional Research Laboratories);

* Phyto-Chemical Drug Discovery/New molecule search;

* Standardisation of Ayurvedic Farmulations;

* Pharmacopoeial Standards Development;

* Documentation & Patent related issues.

5. **Ministry of Agriculture**

- Indian Council for Agricultural Research – development of agro-techniques (50 MAP);
- Agricultural Universities - Medicinal Plants Demonstration Gardens (16 States) & Agro-technique/cultivation;
- National Bureau of Plant Genetic Resources (NBPGR);
- All India Coordinated Project on Medicinal and Aromatic Plants (NBPGR);
- National Horticultural Development Board – scheme of Medicinal Plants

3. **Ministry of Science & Technology (Department of Biotechnology)**

(iv) Conservation of germplasm;

(d) National Gene Banks for MAP (4);

(e) Micro-propogation;

(f) Genetic improvement;

(v) Biotechnological Approach for Herbal/Ayurvedic/New Drug Development;

(vi) Pogramme for G-15 & Asian countries.

ESTABLISHMENT OF THE DEPARTMENT OF INDIAN SYSTEMS OF MEDICINE & HOMOEOPATHY

AN INDEPENDENT DEPARTMENT OF ISM&H WAS SET UP IN THE MONTH OF MARCH 1995 UNDER THE MINISTRY OF HEALTH & FAMILY WELFARE. THE DEPARTMENT BECAME FULLY OPERATIONAL IN DECEMBER 1995 WITH THE APPOINTMENT OF A FULFLEDGED SECRETARY

OBJECTIVES

- TO UPGRADE THE EDUCATIONAL STANDARDS IN THE ISM&H COLLEGES IN THE COUNTRY
- TO STRENGTHEN EXISTING RESEARCH INSTITUTIONS AND ENSURE A TIME-BOUND RESEARCH PROGRAMME ON IDENTIFIED DISEASES FOR WHICH THE SYSTEMS HAVE AN EFFECTIVE TREATMENT
- TO DRAW UP SCHEMES FOR PROMOTION, CULTIVATION AND REGENERATION OF MEDICINAL PLANTS USED IN THESE SYSTEMS
- TO EVOLVE PHARMACOPOEIAL STANDARDS FOR ISM&H DRUGS

UNANI

ORIGIN CAN BE TRACED BACK TO GREEK MEDICINE. CAME TO INDIA THROUGH THE ARABS. UNANI SYSTEM DEALS WITH THE STATE OF HEALTH AND DISEASES IN THE HUMAN BODY BASED ON THE HUMOURAL THEORY.

CONT.

AYURVEDA

AYU + VEDA (Science of life)

HUMAN BEING: BODY + MIND + INTELLECT + SOUL

CONCEPTS

1. FIVE ELEMENTS: (Panch Mahabhuta)	SPACE (Akash)	AIR (Vayu)	FIRE (Agni)	WATER (Jal)	EARTH (Prithvi)
2. THREE DOSHA (TRIDOSHA)	VATA		PITTA		KAPHA
3. THREE TYPES OF DISEASES :	VATA (Dominating)		PITTA (Dominating)		KAPHA (Dominating)
4. 3 TYPES OF DRUGS:	VATA		PITTA		KAPHA
5. 3 TYPES OF FOOD:	VATA		PITTA		KAPHA

6. DISEASE – IS THE IMBALANCE OF VATA, PITTA & KAPHA.

7. HEALTH - IS A STATE OF BALANCE OF VATA-PITTA-KAPHA.

THRUST AREAS OF THE DEPARTMENT

- IMPROVEMENT AND UPGRADATION OF STANDARDS OF EDUCATION IN ISM&H
- STANDARDISATION OF DRUGS.
- RESEARCH AND DEVELOPMENT
- ENHANCING THE AVAILABILITY OF RAW MATERIALS I.E. MEDICINAL PLANTS, MINERALS AND MATERIALS OF ANIMAL ORIGIN ETC;
- INFORMATION EDUCATION AND COMMUNICATION
- INVOLVEMENT OF ISM&H IN THE NATIONAL HEALTH CARE DELIVERY SYSTEM, NATIONAL HEALTH AND FAMILY WELFARE PROGRAMMES

CONT.

INDIAN SYSTEMS OF MEDICINE & HOMOEOPATHY

AYURVEDA

BASED ON VEDAS, DEVELOPED MORE THAN 7000 YEARS AGO, STRESSES ON POSITIVE HEALTH. A BLENDING OF PHYSICAL, MENTAL AND SPIRITUAL WLEFARE. THE SCIENCE OF LIFE

SIDDHA

AGASTHIYAR IS REFERED TO AS FOUNDER OF THIS SYSTEM WHICH IS IN TAMIL LANGUAGE AND POPULAR IN SOUTHERN INDIA.

CONT.

ISM&H INFRASTRUCTURE

(a) Institutionally trained practitioners	4.00 lakhs
(b) Number of non-institutionally qualified practitioners	2.11 lakhs
(c) Colleges	305
(d) Admission capacity per annum in ISM&H colleges	14,204
(e) Number of Drug Manufacturing Units	9,456
(f) Number of hospitals if ISM&H (in Govt. Sector)	2,854
(g) Number of beds in hospitals of ISM&H	49,353
(h) Number of dispensaries of ISM&H (in Govt. Sector)	22,735

EDUCATION

STATUTORY AND REGULATORY BODIES

- CENTRAL COUNCIL OF INDIAN MEDICINE(CCIM)
- CENTRAL COUNCIL OF HOMOEOPATHY (CCH)

CENTRAL COUNCIL OF INDIAN MEDICINE & MATTERS CONNECTED THEREWITH

- A STATUTORY BODY UNDER THE DEPARTMENT OF ISM&H ESTABLISHED IN 1970 UNDER THE INDIAN MEDICINE CENTRAL COUNCIL ACT 1970

OBJECTIVES

- MAINTENANCE OF A CENTRAL REGISTERAR OF ISM PRACTITIONERS AND MATTERS CONNECTED THEREWITH

Eight Branches/Specialities of Ayurveda

1.	**Internal Medicine**	-	**Kayachikitsa**
2.	**Pediatrics**	-	**Kaumarbhritya**
3.	**Psychiatry**	-	**Grahachikitsa**
4.	**Opthalmology & E.N.T.**	-	**Shalakyatantra**
5.	**Surgery**	-	**Shalyatantra**
6.	**Toxicology**	-	**Vishatantra**
7.	**Geriatrics**	-	**Rasayanatantra**
8.	**Knowledge of Virilifics**	-	**Vajikarnatantra**

EDUCATION

Affiliated to the Universities: -

1. Graduate B.A.M.S. degree course of 5½ year duration.
2. M.D. (Ayu) Post Graduate degree of 3 year duration. (45 Institutions in India)
3. Ph.D. - Ayurveda Research degree.

Premier Institutions: -

1. Gujrat Ayurved University – Jamnagar
2. Faculty of Ayurveda – Banaras Hindu University.
3. National Institute of Ayurveda – Jaipur.

Directorate of Indian Medicine/Ayurveda: -

18 state Govts. have separate Directorate of Indian System of Medicine – Ayurveda.

NATIONAL INSTITUTE OF EXCELLENCE

- NATIONAL INSTITUTE OF AYURVEDA (NIA)
- NATIONAL INSTITUTE OF UNANI MEDICINE (NIUM)
- NATIONAL INSTITUTE OF HOMOEOPATHY (NIH)
- NATIONAL INSTITUTE OF NATUROPATHY (NIN)
- MORARJI DESAI NATIONAL INSTITUTE OF YOGA (MDNIY)
- RASHTRIYA AYURVEDA VIDYAPEETH (RAV)

CONTINUING EDUCATION

- STRENGTHENING AND UPGRADATION OF U.G. & P.G.COLLEGES

NATIONAL INSTITUTE OF AYURVEDA (NIA), JAIPUR

- AUTONOMOUS BODY UNDER THE DEPT. OF ISM&H; ESTABLISHED AS PREMIER INSTITUTE IN 1976; CONDUCTS 5-1/2 YEARS DEGREE COURSES IN AYURVEDA SYSTEM OF MEDICINE; ALSO CONDUCTS P.G COURSE IN NINE SUBJECTS IN AYURVEDA

RESEARCH COUNCILS

There are four Research Councils under the Department ; namely,

1. Central Council for Research in Ayurveda & Siddha (CCRAS) - 84 Institutions / Units
2. Central Council for Research in Unani Medicine (CCRUM) - 32 Institutions / Units
3. Central Council for Research in Homoeopathy (CCRH) - 51 Institutions / Units
4. Central Council for Research in Yoga & Naturopathy (CCRY&N)

They initiate, aid, guide, develop and coordinate Scientific research both fundamental and allied relating to the respective system.

CONT.

INDIAN LEGISLATIONS TO REGULATE AYURVEDIC MEDICINE:

- DRUGS & COSMETIC ACT 1940 & RULES MADE THEREUNDER
- MAGIC REMEDIES (OBJECTIONABLE ADVERTISEMENT) ACT

STATUTORY BODIES

- AYURVEDA, SIDDHA, UNANI DRUGS TECHNICAL ADVISORY BOARD
- DRUGS CONSULTATIVE COMMITTEE

STATUS OF AYURVEDIC PHARMACOPOEIA OF INDIA

1. Ayurvedic Pharmacopoeia of India(API – Vol.I & II (Published) - 158 (Plant based Drugs)
2. Ayurvedic Pharmacopoeia of India (API – Vol. III & IV) (Ready for Publication in the year 2000) - 160 Drugs.
3. Ayurvedic Formulatories of India (Part I & II Published) - containing 642 poly herbal formulations.

STATUS OF TESTING LABS
PLIM Ghaziabad.

Pharmacopoeial Laboratory for Indian Medicines at Ghaziabad is the only Government Laboratory engaged in the activities related with Pharmacopoeial standard setting for ISM drugs and testing of ISM drug samples.

Use of Medicinal Plants in Ayurveda in various Pharmaceutical Dosage Form

1. Five forms of raw herbs in simple dosage form:
   (i) Swarasa - Fresh juice
   (ii) Kalka – Paste
   (iii) Kwath – Decoction
   (iv) Phanta – Hot Infusion
   (v) Him, Sheet Kshya – Cold infusion
2. Asava & Arishta (Fermented liquid with self-generated alcohol);
3. Other alcoholic 8 products are: Sura, Varuni, Sidhu, Shukta, Kanji, Tushodaka, Soubeer, Surassera;

DOSAGE FORM OF AYURVEDIC MEDICINES

4. Arka (Distilled plant material with volatile oils);
5. Avaleha & Paka (Confections):
   (c) Modak (Bolus)
   (d) Khand (Sugar mixed powder);
6. Kwatha Churna (Coarse Powders for decoction);
7. Ksheera pak – (Decoction in milk);
8. Gharita (Medicated Ghee – Clarified Butter);
9. Churna (Fine powder);
10. Taila (medicated oils);
11. Lavana (Salts derived from plants);

DOSAGE FORM OF AYURVEDIC MEDICINES

12. Kshara (Salts & Alkali of plant origin);
13. Lepa (Preparation for local application on skin);
14. Vati and Gutika (Tablets & pills);
15. Varti (Suppositories);
16. Netra Vindu (Aschhayotna – Eye drops);
17. Sattva (Dried water extract without boiling) – This is insoluble starchy portion of a drug, which is cool in nature.
18. Ghannasatva (Dried water extract after boiling);

DOSAGE FORM OF AYURVEDIC MEDICINES

19. Varti - Yonivarti (Vaginal suppository)
    - Phalavarti (Anal suppository);
    - Netravarti (Suppository for eyes);
20. Nasya - (a) Nasal drops; (b) Nasal insufflation;
21. Suchivedha – Injectable;
22. Malham (Malhar) – ointments;
23. Ubatana (body/Face pack-paste);
24. Udvartan (Body powders for rubbing over the body parts);
25. Anjana (Fine powders for eyes);
26. Mandura (Herb powders rubbing over the body);
27. Rasa (Herbo-mineral-Metalic combinations).
28. Dhupan – Medicated Fumigation.

Some Important Indian Plants for various Health Disorders

	Indian Name		Disease condition
1.	Ashwagandha (Withania somnifera)	-	Geriatrics problem
2.	Bala (Sida Cordfolia)	-	Neurological disorders
3.	Brahmi (Bacopa monnieri)	-	Memory disorders
4.	Geloy (Tinospora cordifolia)	-	Immuno-modular
5.	Chiraita (Swertia Chirata)	-	Liver disorders
6.	Kutki (Picrorrhiza kurroa)	-	Liver disorders
7.	Gudmar (Gymnema sylvestre)	-	Diabetes
8.	Ashoka (Saraca asoca)	-	Uterine Tonic
9.	Satavari (Asparagus racemosus)	-	Anti-Ulcer, Aprodisiacs
10.	Amala (Emblica officinalis)	-	Rasayana, Geriatics
11.	Arjuna (Terminalia arjuna)	-	Cardiac disorders
12.	Guggalu (Commiphora wightii)		Cholesterol & Arthritis

STANDARDIZATION OF HERBAL MEDICINES

BY

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BEING A LECTURE PRESENTED AT AN INTERNATIONAL WORKSHOP ON "STRATEGIES TO STRENGTHEN THE UTILIZATION OF MEDICINAL AND AROMATIC PLANTS IN THE NATIONAL HEALTH CARE SYSTEM"

11 - 13TH JULY 2000

1. INTRODUCTION

In 1996, the Conference of Drug Regulatory Authorities considered the commercial exploitation of herbal medicines through the over-the-counter label products. In 1989, a similar Conference in Paris specifically drew the attention of WHO to the need to prepare model guidelines containing basic elements of legislation designed to assist those countries who might wish to develop appropriate legislation and registration of herbal medicines. In 1991, the Program on Traditional Medicine of WHO published Guidelines for the Assessment of Herbal Medicines (WHO/TRM/91.4). The objective of these guidelines is to define basic criteria for the evaluation of quality, safety, and efficacy of herbal medicines and thereby assist national regulatory authorities, scientific organizations, and manufacturers to undertake an assessment of the documentation/submission/dossiers in respect of such products. With these in mind, the standardization of herbal medicines became imperative. This is more so, if they are intended to be used as standard medicines in health care delivery. Such standardization will make it possible for quality, efficacy and safety to be ensured in their use because it involves quality specifications and limits for the plants used.

WHO DEFINES HERBAL MEDICINES:
As finished, labeled medicinal products that contain as active ingredients aerial or underground parts of plants, or other plant materials, or combinations thereof, whether in the crude state or as plant preparations. Plant material includes juices, gum, fatty acids, essential oils, and any other substances of this nature. Herbal medicines may contain standard excipient in addition to the active ingredients. Medicines containing plant material combined with chemically defined active substances, including chemically defined, isolated constituents of plants, are not considered to be herbal medicines. Exceptionally, in some countries herbal medicines may

also contain, by tradition, natural organic or inorganic active ingredients which are not of plant origin.

The World Health Organization, in recognition of the immense value of Herbal Medicine to Primary Health Care, has advocated for the proper identification, sensible exploitation, scientific development and appropriate utilization of Herbal Medicines which provide safe and effective remedies in Medicare. In many countries, especially in Asia, Herbal Medicine has become an integral part of the health care delivery system on the same basis as Orthodox Medicine. However, in most countries in Africa, this is not yet the case. Even in the latter situation, Herbal Medicine is recognized as an important component of the health care system especially among the rural dwellers who constitute about 70% of our population. Furthermore, in both rural and urban communities, many people depend partly on Herbal remedies for their Primary Health Care needs. Even in the developed countries, the popularity of crude herbal products is on the increase. In these technologically advanced societies, consumers' preference is shifting from purely synthetic to natural based drugs and this is dictating the basis for the resurgence in the utilization of such products.

It is therefore obvious from these realities that due to the inherent value of Herbal Medicine and the immense socio-economic demands for adequate pharmaceutical supplies in the rural areas, transportation difficulties, the needed expertise for the rational use of drugs, the availability and cost of these products, Herbal Medicine remains the most viable way to bridge the gap in Medicare. It must however, be emphasized that important as it is to aim at bridging the gap between the availability and the need for orthodox medicine, what has a lasting influence on our people and other in the world is the fulfillment in self -reliance vis-à-vis development of herbal medicines which are safe and effective. Tables II and I indicate some orthodox medicines and standardize purified extracts from medicinal plants.

In this paper, standardization of herbal medicines will be considered under the following: botanical, chemical, microbiological, pharmacological, toxicological, quality control, pharmaceutical and clinical aspects.

2. GLOBAL RESURGENCE IN THE USE OF PHYTOPHARMACEUTICALS

According to Farnsworth (1989), about 28% of 33,000 species of monocots, dicots, gymnosperms, pridophytes, bryophytes and lichens in NAPRALERT database have been used ethnomedically. In the Republic of China, 5000 of the 35,000 plant species growing there are used as remedies in Chinese Traditional Medicine i.e. about 14%. The conservative estimate of the number of higher plants on Earth is 250,000 species. Apparently, 14 -28% of these plant (i.e. 35 -70,000 species) have been employed in herbal medicine in different parts of the world. The developing countries are endowed with an abundant biodiversity and a rich heritage in the use of herbal medicine (Vom Puyvelde, 1992). It has been estimated that only about 1% of plants have been scientifically evaluated.

The current increase in the use of plant-base drugs may be associated with the following factors:

I. High cost (about 600 million US dollars) and long time (12 -20 years) invested in the development of a new drug (Rathman, 1994).

ii. Relatively high incidence of toxicity and side effects of synthetic drugs (e.g. iatrogenic diseases)

iii. Non-renewable source of basic raw materials. About 80% of synthetic pharmaceutical chemicals are obtained from fossil resources like petrochemicals.

iv. Environmental pollution by the Chemical Industry.

v. Cost of orthodox medicines.

vi. Non-availability in developing countries.

vii. Clinical limitations, especially in the management of some chronic diseases.

On the other hand, phytopharmaceuticals have the following advantages:

I. Long history of use.

ii. Renewable source of raw materials.

iii. Both cultivation and processing are environmentally friendly.

iv. Locally available in developing countries.

v. Plants are generally depository of new chemical moieties.

vi. Recent break-throughs e.g. taxol, artemisinine.

Table 1: Some medicines of plant origin currently used in modern therapeutics

Table 1: Medicines of plant origin	
Drug	Plant
Atropine	Atropa belladonna Doboisia myoporoides
Ajmaline	Rauwolfia vomitoria Rauwolfia serpentina
Cocaine	Erythoxylum coca
L. Dopa	Mucuna deeringiana
Digitoxin	Digitalis lanata
Emetine	Cephaelis ipecacuanha
Ephedrine	Ephedra spp.
Forskolin	Coleus forskohlii
Hyoscyamine	Datura spp. Hyoscyamus muticus
Menthol Mentha spp.	Mentha spp.
Morphine	Papaver spp.
Ouabain	Strophanthus gratus
Papain	Carica papaya
Physostigmine	Physostigma venenosum
Picrotoxin	Anamirta cocculus
Pilocarpine	Pilocarpus jaborandi
Quinine	Cinchona spp.
Quinidine	Cinchona spp
Reserpine	Rauwolfia serpentina
Scopolamine	Datura metel Hyoscyamus niger
Theobromine	Theobroma cacao
Theophylline	Theobroma cacao
D-Tubocurarine	Strychnos spp. Chododendron spp.

Vincamine	Vinca minor
Vinblastine	Catharanthus roseus
Vincristine	Cathaanthus roseus
Yohimbine	Pausinystalia yohimbe

The phytochemical agents mentioned in table I are found in the internationally recognised pharmacopoeias or phytotherapeutic index[2]

Table II: Medicinal plants used in the production of standardaised whole or purified extracts.	
Plant	Standardised extract
Aloe spp	Dry extract
Atropa belladonna	Dry extract Tincture
Capsicum annuum	Oleoresin
Centella asiatica	Purified extract
Cephaelis ipecacuanha	Soft extract
Cynara scolymus	Dry extract
Digitalis purpourea	Whole extract
Glycyrrhiza glabra	Whole or purified extract
Panax ginseng	Dry extract
Prunus africana	Purified extract
Rheum officinale	Dry extract
Valeriana officinalis	Dry extract Tincture
Zingiber officinalis	Dry extract Oleoresin

3. BOTANICAL STANDARDIZATION

BOTANICAL STUDY

The botanical definition including the genus, species and authorities should be supplied and authenticated by indigenous national authorities so as to facilitate the correct identification of the plant. This is very important because of similarities between the physical characteristics of many plants. Both macroscopy and microscopy of the plant parts used for formulating the herbal medicine should be established. Furthermore, a description of the part of the plant which is used for preparing the herbal medicines should be indicated. For example, fresh or dry plant parts like leave, flower, root, stem, fruit, etc. The season, ecological characteristics and time of the day of collection should be noted, since these factors affects the chemistry and pharmacology of plant extracts. It is advised that the voucher specimen representing each lot of the plant material which has been processed should be appropriately authenticated by a qualified botanist and the specimen should be stored for at least ten years. A lot number should be assigned which should appear on the product label.

4. CONSERVATION OF MEDICINAL PLANTS

From the Atlantic shore to the most northerly parts of Africa, there is a marked climatic change embracing humid coastal lowlands, sub-humid uplands and semi-arid zones. Some plants are adapted to specific ecological zones while others are ubiquitous. It is therefore not surprising that African region has one of the richest biological diversities in both flora and fauna in the world. However, the annual bush burning for game, deforestation, increased land utilization for industrial development and farming as well as decertification are threatening the very survival of many medicinal plants found in the diverse ecological nitches of Africa (Wambebe, 1994).

It is therefore urgent for us to ensure that policies and practices necessary to conserve plants and animals which save lives are put in place (Akerele, 1988). Systematic campaigns are necessary at all levels and co-operation of traditional rulers and government officials is essential for success. Adequate penalties may be evoked to ensure compliance with the regulations on this important issue. Federal,

State and Local governments as well as private organizations and individuals should be encouraged to establish botanical gardens for the cultivation and conservation of such plants. The Institute is collaborating with the Federal Ministry of Agriculture and Natural Resources on this matter. The Institute , in our research and development efforts, is very conscious of the parts of plants used such that the plants do not eventually become extinct especially when both the economic and medicinal significance of such plants become apparent to the farmers and plant collectors.

5. CHEMICAL STANDARDIZATION

The chemical studies should determine the importance of using the extracts which correlate to the way in which the original recipe is utilized as a reference material in all specimen studies. For example, if the plant part is soaked in ethanol before it is used then the total ethanol extract will be used as a reference specimen- while if the plant material is boiled in water, then water extract would be the appropriate reference material. However, in each of such cases, the solvent should be removed from the material prior to use. The ultimate goal of the chemical evaluation is to identify and characterize the structure of the pharmacologically active constituents. While such studies are progressing, if other evaluation data indicate that the phyto-pharmaceutical is effective and safe for the disease in question, pharmaceutical formulation and initial clinical trials can commerce after the product has been standardized Wambebe, 1996). In such a situation, it would be important to characterize substances or mixture of substances through chromatographic fingerprinting to ensure consistent quality of the products. HPLC can also be utilized for chemical standardization (Sharma, 1992; 1993; Fomi, 1980; Wagner, 1984). The chemical evaluation should endeavour to identify all the characteristic constituents and also define their acceptable limits. Ideally, the component used for clinical standardisation should possess the desired pharmacological activity.

6. MICROBIOLOGICAL STANDARDIZATION

If the primary use of the herbal medicine is to combat microbes then the anti-microbial potential of the preparation should be determined. In such a situation, like other screening procedures, standard anti-microbial screening protocols for the specified disease should be used. The anti-microbial screening data should be interpreted along with the pharmaceutical and toxicological data which will then suggest whether further scientific evaluation is necessary. When the herbal medicine is not intended to be used primarily as an antimicrobial agent, its microbial load should be determined and limit established following the broad WHO guidelines on purity.

7. PHARMACOLOGICAL STANDARDIZATION

Both intensive and extensive pharmacological studies should be conducted using all the fractions including the total crude ethanol or water extracts. The intensive studies should embrace use of appropriate animal models, tissue, cell lines and other in vitro techniques for the particular disease for which the herbal medicine is eventually intended to be used. The extensive studies will be necessary so as to identify possible side effects of the herbal medicine (Wambebe 1996). Where there are no existing laboratory models for the disease, it would be important to develop a suitable model as part of the project Dhawan, 1995).

8. TOXICOLOGY EVALUATION

It has been stated by WHO that the most critical assessment of herbal medicine is safety evaluation. Although Farnsworth indicated that phyto-toxicity is very low, nonetheless, from scientific, professional and moral viewpoints toxicological assessment must be conducted on all herbal medicines intended for either veterinary or human use. Most herbal medicines are obtained from genuine practitioners have been used in ethno-medicine for many centuries. Thus, it can be assumed that only the safe herbal medicines have withstood the test of time. Nonetheless, standard toxicological protocols should be

employed for acute, sub-chronic and chronic toxicity tests. Such data is mandatory for the registration of the product with National Health Authorities. It would also enhance the confidence of Health Professionals in the use of herbal medicines.

9. CARCINOGENECITY AND MUTAGENIC EVALUATION

Since some of the herbal medicines are needed for the management of chronic diseases, longterm use may evoke carcinogenicity and or mutagenicity. There is also the fact that herbal medicine used in it native form may contain both carcinogenic and anti-carcinogenic constituents. For example, *Zingiber officianale* contains both carcinogenic and anti-carcinogenic constituents. However, chemical purification leading to separation of individual constituents will result in removal of any native antagonist in the preparation. It is therefore of vital imporatnce that these tests are conducted on all crude, semi-purified and purified samples.

10. PHARMACEUTICAL STANDARDIZATION

The procedures regarding processing and formulation of herbal medicine should be in accordance with Good Manufacturing Practice (GMP).

Plant preparations include comminuted or powdered plant materials, extracts, tinctures, fatty acids or essential oils, expressed juices and preparations whose production involves a fractionation, purification or concentration process. If any other substance is added during the manufacture to adjust the plant preparation to a certain level of active or characteristic constituents or for any other purpose, the added substances should be mentioned in the procedure.

The manufacturing procedure and formula including the amount of excipients should be decreibed in detail. A finished product specification should be defined. A method of identification, and where possible quantification of the plant material in the finished

product should be defined. If the identification of an active principle is not possible, it should be sufficient to identify a characteristic substance or mixture of substances (e.g. "Chromatographic fingerprint") to ensure consistent quality of the product. The finished product should comply with general requirements for particular dosage forms.

For imported finished products, confirmation of the regulatory status in the country of origin should be required; the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce should be applied. The physical and chemical stability of the product in the final marketing container should be tested under defined storage conditions and the shelf-life should be established.

As many herbal remedies consist of a combination of several active ingredients, and as experience on the sue of traditional remedies is often based on combination products, the assessment should differentiate between old and new combination products.

The labelling of the products and the package insert should be understandable to the consumer/patient. The package information should cover all necessary information on the appropriate use of the product.

According to "WHO Guidelines for the Assessment of Herbal Medicines", the insert should include:

- name of the product
- quantitative list of active ingredient(s) - if known
- dosage form
- indications
- dosage (if appropriate, specified for children and the elderly)
- mode of administration
- duration of use
- major adverse effects, if any

- overdosage information
- contraindications, warning, precautions and major drug interactions
- use during pregnancy and lactation
- expiry date
- lot number
- holder of the marketing authorization
- date of preparation.

It should be noted that not all the information ideally require may be available. Therefore, drug regulatory authorities should determine their minimal requirements. Such requirements will vary depending on the disease being targeted and national health priorities and policies.

11. QUALITY STANDARDIZATION OF RAW MATERIAL

The general protocols followed for the standardization of raw material would usually involve the following tests;

Authentication: the plant material is collected from an appropriate location, time of the day and stage of growth is authenticated by a taxonomist.

Foreign Matter: Plant parts other than what constitutes the drug are considered as foreign matter. Medicinal plant material should be entirely free from soil, stones, dust, insects, animal excreta. etc.

Organoleptic Evaluation: Organoleptic examination involves organs of sense and includes the macroscopic appearance of the drug, its odour and taste, occasionally the sound or "snap" of its fracture and the feel of the drug to the touch.

Microscopic Examination: Microscopic examination of the plant is not only essential to the study of adulterants but it is also indispensable in the correct identification of the material. Diagnostic microscopic

features are of immense value in standardization. Quantitative microscopy like stomatal number, stomatal index and palisade ratio is useful in differentiating closely allied species.

Volatile Matter: The volatile matter is determined by steam distillation of the plant and analysed using GLC.

Ash Value: The presence of ash in medicinal plant materials is determined as total ash, acid insoluble as and sulphated ash. When vegetable drugs are incinerated, they leave an inorganic ash which in the case of many drugs varies within fairly wide limites and these values are of significance for the purpose of evaluation of the raw material.

Extractive Value: The determination of extractable matter refers to the amount of medicinal plant material extracted with solvents. Such extractive values provide an indication of the extent of polar, medium polar and non-polar components present in the medicinal plant material.

Chromatographic Profile and Marker Component: of the many chromatographic methods presently available, thin layer chromatography (TLC) has become widely adopted for the rapid and positive analysis of plants since the time required for the demonstration of most of the characteristic constituents by TLCis very short. In addition to qualitative detection, TLC also provides semi-quantitative information on the main constitutents of the plant and thus enables an assessment of drug quality. Furthermore, TLC provides chromatographic finger-print. It is, therefore, suitable for monitoring the identity and purity of drugs, and for detection of adulteration and substitution. TLc-densitometer scanner has been used for obtaining fingerprint profile is extracts of many drugs introdiced into clinical trials. High Pressure Liquid Chromatography (HPLC) has also been employed in standardizing hepatoprotective and anti-asthmatic herbal medicines.

Pesticide Residues: The use of pesticides has greatly reduced the presence of insects, fungi and moulds in food. Medicinal plants are therefore liable to be affected by pesticide residues which accumulate from agricultural practices of spraying soils during cultivation and through the administration of fumigants during storage. Since many medicinal plant preparations are taken over long periods of time, limits for pesticide residues should be established following the recommendations of the Food and Agricultural Organization (FAO) and the WHO.

Determination of Heavy Metals: Contamination of medicinal plant materials with arsenic and heavy metals(like cadmium and lead) can be attributed to many causes such as environmental pollution and traces of pesticides. The limits (parts per million) of such heavy metals in medicinal plants should remain within official specifications.

Microbial Contamination: Medicinal plant materials normally carry a great number of bacteria and moulds, often of soil origin. Aerobic spore forming bacteria frequently predominate. Current practices of harvesting, addling and production often cause additional contamination and microbial growth. The determination of E. coli and aflatoxin is recommended.

Radioactive Contamination: Irradiation, may have een used as a procedure for microbial decontamination and sterilization of plant materials (after harvest), packaging materials, intermediate products, bulk materials and finished products. WHO, guidelines can be used for this assessment.

12. QUALITY STANDARDIZATION OF HERBAL MEDICINES

Quality of phyto-pharmaceuticals must be as high as that of other medicinal products. It may not be possible to evaluate the specific chemical entity when the pharmacologically active moiety is not known. In most cases, as a general procedure, elaborate and stringent chemical analyses are not conducted for medicinal plant materials

even when the active ingredients are known. For example, much of the ginseng or valerian is bought and sold on the basis of its sensory characteristics, rather like tea. For medicinal purposes, ginseng should be assayed for its ginsenoside content and valerian for its valepotriates.

Standardization problem arises from the complex composition of drugs/which are used in the form of whole plant, parts of the plant(s) and of plant extracts. Though these inert accompanying components may not directly influence the therapeutic value of the product, it is recommended to use the complex mixture because these inert components might influence bioavailability ande excretion of the active component. Furthermore, inert plant components may enhance the stability of the active component, minimise the side effects, and manifest additive or potentiating effect on the active moiety.

Another problem usually encountered in the quality control of plant drugs is that of sampling. It is obvious that the reliability of any quality control assessment depends heavily upon how well the sample represents the whole batch. Because of the specific characteristics of medicinal plant materials, especially their lack of homogeneity, special handling procedures should be employed in relation to sampling.

Recommended procedures include:

- Inspecting each container or package for conformity with monographs or phamacopeial requirements.
- Check for physical damage of packaging and storage conditions which may influence quality or stability.
- Checking the contents for organoleptic characteristics
- Average samples by pooling and quartering, making sure that each portion is representative of the bulk.
- Retaining a portion of each final sample for reference and re-test purposes.
- Contents of retail packages should be pooled and mixed before proceeding with specific QC tests.

The analytical protocol of vegetable drugs must take account of the fact that the material to be examined has a complex and inconsistent composition. Therefore, the analytical limits cannot be so precise as for the pure chemical compounds. Vegetable drugs are inevitably inconsistent because their composition and hence their evaluation may be influenced by several factors such as age and origin, harvesting period, method of drying, etc.

In order to reduce the causes of these inconsistencies, cultivated rather than wild plants which are often heterogenous in respect to the above factors and consequently in their content of active principles should be used. The purpose of standardizing medicinal plant products is obviously to ensure consistent therapeutic efficacy.

13. PRODUCTION OF STANDARDIZED HERBAL MEDICINES

Quality assurance of herbal remedies rely upon good manufacturing practices with adequate batch analysis and standardised methods of preparation. Various processes used in the manufacture of herbal drugs lack standardized methods of preparation. Various processes used in the manufacture of herbal drugs lack standardize methods. Thus, the same herbal medicine prepared by two different manufacturers may vary in its potency and even the physical appearance. Creating uniform standards for the process of manufacturing has thus become very difficult. Large scale commercialization of herbal medicines necessitates scientifically evolved standardized methods of the production (Sharma, 1993) of phytomedicines. General protocols of standardized plant drug production are given in the figure.

14. CLINICAL EVALUATION

Clinical evaluation of a new drug commences when all the laboratory data have demonstrated safety of the products and potential clinical usefulness. Pharmaceutical formulation must have been achieved at

this stage. Clinical evaluation is divided into four phases. Phase I is the initial demonstration of the drug in healthy human volunteers. The objective is to investigate the safety of the drug in healthy volunteers. It is also appropriate at this stage to monitor the kinetic profile of the drug. Phase II is the initial demonstration of the new drug in patients. The objective is to measure efficacy and safety of the drug. Dose adjustment and clinical kinetic studies are also assessed at this phase. The population of patients involved at this phase is small (e.g 100). In phase III the efficacy, safety and dose studies are extended to a larger number of patients (e.g 1000) in specified multi-centre hospitals scattered throughout the countries. In this phase, comparison with other available treatments is undertaken. The study design should allow definite comparision between the test drug and the possible or alternative treatment. Thus, double blind studies are the rule in this phase. Once the drug has successfully passed through phases 1-3 of clinical evaluation, it can then be registered for distribution. But post-market surveillance of efficacy and safety must continue. This is regarded as Phase IV of the clinical evaluation. The overriding consideration of the clinical evaluation of any drug is safety, efficacy and well being of the patient.

15. CONCLUSION

The objective scientific evaluation of herbal medicine, adequate planning, application of modern technology and a rational approach will enhance the incorporation of proven herbal products and practices into the public health care deliver system. Through proper evaluation and scientific analysis with the aim of ascertaining the therapeutic validity, toxicology, dosage and side effect- the basis for registration of herbal medicine will be established. A well articulated policy on the objective integration of herbal medicine is an absolute pre-requisite for the establishment of the socio-political commitment of the Government (Wambebe, 1993). Allocation of funds, and proper management and relevant manpower development are essential factors necessary for the successful execution of this policy. It is encouraging to note that China and India developed herbal medicines and trained their various categories of health personnel with

considerable success. The world will benefit maximally from the fruit of the application of modern scientific technology on the development of herbal medicine.

In order to achieve the desirable goal of developing herbal medicines, close National and International cooperation and collaboration will be absolutely essential between governments and universities, traditional medical practitioners and health professionals, pharmacologists, agronomists, botanists and interested international organizations.

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PRESENT TRENDS IN MEDICNAL AND AROMATIC PLANTS RESEARCH: AN AFRICAN PERSPECTIVE

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(Paper presented at the Workshop organized by the International Centre for Science and High Technology, ICS-UNIDO and NIPRD on " Strategies to Strengthen the Utilization of MAPs in the National Health Care System", Abuja, Nigeria from 11 to 13 July 2000)

1. Demand and Supply of Medicinal and Aromatic Plants

The demand for medicinal plants has recently increased globally. This is mainly due to the resurgence of interest in natural products, increased worldwide awareness in the value of traditional system of medicine and the search for new drugs to cure major diseases including cancer and AIDS. In the USA and in many other countries in the world, alternative or complementary medicine, which relies heavily on medicinal and aromatic plant is now taken more seriously than ever before. An entire issue of the prestigious Journal of the American Medical Association, Vol. 280, No. 11 (Nov. 1998) was devoted to alternative medicine and lists nine plants shown below to be the most popular and widlely used herbal medicines of that country.

- Bilberry, eye health
- Boswellia (Ayurvedic), anti-inflammatory
- Echinacea, immune stimulant
- Garlic, heart health
- Ginko, age related memory loss
- Kava, for anxiety
- Saw Palmetto, BPH
- St. John's Wort, depression
- Valerian, insomnia

The economic significance of herbal therapies is growing from year to year by leaps and bounds. Eisenberg et al. (1998) estimated, for USA alone, the total 1997 out-of-pocket expenditures relating to alternative therapies to be 27 billion and assert that this exceeds the 1997 out-of-pocket expenditures for all US hospitalizations. Germany dominates the European trade in medicinal and aromatic plants with an annual import exceeding 40.000 tons of 'botanicals' valued at US$109 million (Kuipers, 1997).

This enormous demand for medicinal and aromatic plants is generally met by indiscriminate harvesting of natural flora including those in forests. Even in Europe where nearly 2000 medicinal and aromatic plants are used commercially every year, at least 1200-1300 are native European species, the vast majority of which are taken directly from the wild (Kelso, 1998). Such continued and indiscriminate use of wild plants accelerates the rate of their extinction. Furthermore, wild plants are often heterogeneous in terms of active constituent content and this leads to difficulties in assuring standardized quality, a problem that can be alleviated if plants are cultivated and systematically processed.

Large scale cultivation of medicinal plants is practiced only in few countries in the world and this is done only for those plants for which there is continuous demand.

Recently field cultivation of medicinal and aromatic plants is re-expanding in Europe. In Germany for instance, medicinal and aromatic plants were cultivated in 1996 on 7000 ha (0.6% of the total arable land), an increase of 100% compared to 1991-94 period (Bueter *et al.*, 1998).

However, cultivation of medicinal and aromatic plants is not yet developed in Africa. The scarcity of plant species causes traditional healers and others to travel long distances to get medicinal plants from the wild. Destructive harvesting techniques which aim at maximizing collections are quite common nowadays and this is threatening many African species such as *Prunus africana* (Cameroon), *Griffonia simplicifolia* (Ghana), *Harpagophytum procumbens* (Botswana and Namibia) etc. Vivid account of how serious the situation is has been given by Cunningham (1997).

The low cost of wild collected materials and the fact that cultivation requires considerable investment may be some of the reasons for the still limited level of cultivation of medicinal and aromatic plants in Africa. However, the increasing demand for medicinal plants and the requirements for high quality products clearly shows the need to cultivate and process these plants in areas having the same climate and soil as the natural habitat.

Even in South Africa, despite the estimated annual medicinal plant trade of 20,000 tons, valued at US$ 60 million, little cultivation takes place and the trade relies mainly on indigenous plants which are generally harvested from the wild (Mander, 1998).

Small scale cultivation of medicinal plants takes place in Africa in home gardens. It is customary for households in rural and those in peri-urban towns to have home gardens. Home gardens are small-scale traditional farming systems practiced around the house and used primarily for growing crops, spices and medicinal plants for home consumption. Home gardens play an important role in healthcare and conservation of biodiversity. Asfaw (1998) listed over 60 medicinal plants that are grown commonly in home gardens in Ethiopia.

2. Research in Medicinal and Aromatic Plants of Africa

Chemical studies not only contribute to advancing knowledge but will also help in finding ways and means of adding value to natural products in the countries of origin so that the producing communities derive more benefits and therefore become more aware of the advantages of the sustainable utilization of their resources.

At the present time, much effort is directed by the scientific community from Africa and elsewhere towards the study of the botany, chemistry and pharmacology of African plants and considerable amount of information is now available in the literature. It is important to keep abreast of these developments in order to draw lessons of relevance to the establishment of medicinal plant industry.

A database that we are building on results of phytochemical studies on plants originating from Africa and appearing in leading natural products journals clearly shows the rise in the number of scientific reports on the chemistry of African plants. Nearly 1500 papers were published on African plants in the well known international journal *Phytochemistry* in the period 1963-97. In the same period nearly 1000 papers appeared on African plants in the other two natural products journals namely *J. Nat. Prod.* and *Planta Medica*. Large number of reports were on plants from Cameroon, Egypt, Ethiopia, Kenya, Nigeria, Tanzania and South Africa.

Typically most of the chemistry oriented papers report isolation and characterization of novel compounds from the African flora. Other studies deal with

the biological and pharmacological activities of crude extracts or isolated compounds. The choice of the plants is sometimes based on folk medicine, use in commerce, chemotaxonomic significance and biological activities. In the biologically inclined studies workers usually attempt to establish if there is a scientific basis in the traditional medicinal claims for the use of the plants.

Much of the chemical and other studies on African plants were conducted in the past in laboratories in far away lands. In many instances, this hindered continuous and thorough studies on plants of interest in particular when handling specimens that contain unstable substances. For instance, although several attempts to study the chemistry of the African stimulant plant Khat (*Catha edulis*) using mainly dried leaves were made starting from the 1870's by German and other chemists, its active substance cathinone, with a surprisingly simple structure could be discovered only in 1975 when it was possible to carry out research on fresh leaves (Szendrei, 1980).This illustrates the importance of conducting chemical studies on African plants in Africa itself where it is possible to get regular supply of fresh materials.

3. Processing of Medicinal and Aromatic Plants of Africa

In most African countries plant medicines are sold in raw form in medicinal plant markets with very little processing and value-adding to products. It has been estimated (Wambebe, 1998) that production of simple medicinal plant extracts increases the value added by 10 fold. Some African countries like Botswana, Madagascar and Cameroon are producing such extracts. In Nigeria a pilot plant was established at the National Institute for Pharmaceutical Research (NIPRD), where three plant based drugs, MIPRISAN, NIPRIPAN and NIPRIFAN were developed as anti-sickle cell, anti-ulcer and anti-fungal agents respectively (Wambebe, 1998).

Essential oils obtained usually by steam distillation of aromatic plants are one of the most important natural products that are widely used in the food, cosmetics and pharmaceutical industries. International trade in essential oil is now worth billions of US dollars, indicating the enormous economic importance of these products.

Due to simple process requirements for production of essential oil many developing countries are engaged in this venture and are deriving considerable benefits from it. The area of essential oil is an excellent entry point to the medicinal and aromatic plants industry and is also one of the best ways of deriving value-added products from plants. Essential oil production is developing rapidly in Africa in particular in Egypt, South Africa and Madagascar, and small-scale enterprises are also mushrooming in many other African countries. The International Development Research Center (IDRC) supported R&D activities in the are of essential oils in several African countries including: Benin, Ghana, Guinea, Morocco, Rwanda, Togo and Zimbabwe (Gasangayire, 1997). The project focused on cultivation, pilot plant distillation, quality control and market issues for indigenous and introduced plants. It also attempted to promote creation of small scale enterprises in these countries.

UNIDO is also making significant contributions in Africa to the development of the industrial utilization of aromatic and medicinal plants in particular by designing and constructing pilot plants. De Silva (1998) has published an appropriate design and states that it can be fabricated with eas in any country where the facilities for stainless steel welding is available. UNIDO also supports initiatives that promote processing of aromatic plants in rural areas.

First, focus should be on processing resources that are abundantly available and are now exported in raw form. For instance, the potential production of olibanum

or frankincense in Ethiopia alone is 23,000 tons per annum (Coppen, 1995) and there is more of this product in the Sudan, Somalia, Kenya and Senegal. Because supply exceeds demand, the price for Grade 1 olibanum is only $1-2/kg. Some processing in the countries of origin may result in modest gains of income. Like olibanum it is possible to list many other resources that are available in abundance in Africa that could be processed on a wider scale to yield essential oils that are highly valued by aromatherapists and others.

Second, much attention should be accorded to African plants that enjoy extraordinary world wide demand but for which the resource base is being depleted. African industries should ear mark such species and invest in R&D in order to find ways and means of conserving, multiplying and sustainably exploiting them in the sprit of the Convention on Biological Diversity (CBD), which has opened new avenues to protect Africa from biopiracy and outright pillage of its natural resources.

An innovative and exemplary venture in this connection is one conducted at the Silver Glen Nature Reserve (SGNR) located near Durban, South Africa. The Reserve is maintaining nurseries in particular for those medicinal plants that are sold in markets and road sides by vendors and that are at the verge of extinction. The seedlings are sold to interested members of the community who grow them in farms and home gardens. Through this initiative, *Warburgia salutaris*, a well known South African medicinal plant that is endangered and depleted, has been successfully cultivated and thus saved from imminent extinction. The center also offers workshops on cultivation techniques and conservation issues to medicinal plant vendors.

Third, introduced species that do well in Africa should be widely cultivated and utilized. For instance, clove (an aromatic plant and spice) and pyrethrum (a natural insecticide) do not originate from Africa. However, Tanzania and Kenya respectively are the world's largest suppliers of these two species. Successful attempts in the formulation and applications of pyrethrum have been made in Kenya, where the Pyrethrum Bureau runs a Research Center and regularly publishes a scientific journal, the *Pyrethrum Post*. Likewise, *Pinus* species originally from the Americas, are now cultivated in some African countries and the resin is processed in Kenya for production of rosin and turpentine (Njenga, 1995).

4. Issues of Concern: Intellectual Property Right (IPR)

The subject of intellectual property rights (IPR) in the realm of natural products has not been fully addressed yet in the context of Africa. Protection of IP in African countries is at quite a low level when compared to developed countries. It is generally acknowledged that African countries should take measures to protect the heritage of their traditional knowledge so that the respective communities benefit from this heritage. Despite the good progress made since the declaration of the Convention of Biodiversity (CBD), the mechanism by which this will be realized is not yet in place and there is strong need that it be spelt out as soon as possible.

Equally challenging is the issue of bioprospecting. How does one deal with a researcher or a company that takes away a biological material without proper agreement with a source country and benefit from it? Isn't such act akin to trespassing or poaching? Should such a scientist be allowed to publish the results if the material was collected without compliance with the CBD?

Take for instance the paper by Kernan *et al.* (1998) of Shaman Pharmaceuticals USA, in which several antiviral compounds from the Tanzanian medicinal plant *Markhamia lutea* were reported. The authors state that the plant was

collected with the assistance of locals working for a Rural Development Association and vouchers were deposited at the company's headquarters in the USA.

A controversial collecting mission to Ethiopia took place recently by an Australian group that took to its home country legume germplasms from previously untapped area near the source of the Blue Nile. The collectors state that "the farmers were highly cooperative and provided supplementary material from their seed stocks"[11]. This collection was done under the guise of scientific exchange and training of young scientists.

In another instance, Kubo and Kinst-Hori of U.S.A.(1999) purchased from markets in Nairobi, Kenya and Arusha, Tanzania three medicinal plants, collected the plants also from the wild to ascertain their botanical identities, undertook bioassay guided fractionation and discovered a potent tyrosinase inhibitor. Under such circumstances, does an investigator outside the source country have the right to handle biological materials in this manner? If the bioactive compound has activity of interest and is worthy of commercialization, what benefits can one claim on behalf of the source country?

A question for discussion and reflection follows. Should such individuals or research groups be allowed with impunity to patent, publish or make any use at all of the results of their investigations?

5. The Challenges Ahead

It is not enough to speak only of protecting our natural resources from being exploited by bioprospectors from outside. At the same time, the African scientist should strive to be in the forefront in research and development efforts geared towards rational utilization and conservation of these resources. It is therefore imperative to convince both governmental and private institutions in the region to invest as much as possible in the area of natural products. Not doing so will be at the detriment of this most valuable but endangered natural resource, that must be used rationally and passed on to future generations.

One immediate course of action is to take measures that aim at adding value to natural products in the countries of origin so that the producing communities derive more benefits from them and therefore become more aware of the advantages of the sustainable utilization of these resources. The global rise in the value of natural products makes one more optimistic than ever before about positive returns and it would be a pity if Africa does not get its share from the enormous benefits of such natural resources endowed to it by nature. In order to enhance Africa's role and to increase the returns it gets from natural products, one must encourage the establishment of natural products enterprises in the region. The benefits that would accrue from such endeavors would help accelerate the science of natural products not only in the region, but also globally through the enhanced contribution of African scientists.

There is enormous potential in Africa to develop a profitable industry based on traditional herbal remedies and aromatic plants. To ensure that this is successful one must before it is too late take measures to conserve in particular vulnerable and slow-growing species in their natural habitat and promote the cultivation of those species where sustainable harvest is possible. The importance of promoting R&D efforts in Africa in the area of medicinal and aromatic plants directed at value-adding cannot be overemphasized.

Much remains to be done in Africa to integrate phytomedicine with modern medicine. More effort should therefore be made to make modern African physicians aware of the value of alternative medicine so that they resort to herbs and other natural products while treating their patients. Like the increasing number of medical schools in China, USA and Europe that are including alternative medicine in their curriculum, those schools in Africa should also follow these trends.

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OWNERSHIP AND SUSTAINABILITY ISSUES OF HERBAL MEDICINES

By

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1.0 PREAMBLE

There is a growing recognition that biological diversity including medicinal plants is a global asset of tremendous value to present and future generations. At the same time, the threat to species and ecosystems has never been so great as it is today. Loss of species caused by human activities continues at an alarming rate. Throughout the world, people use many wild species for food, medicine, clothing, shelter, fuel, fiber, income generation and the fulfilling of cultural needs. Wild species are vital to the economic and social welfare of many communities. However, pressure from growing populations and the adoption of not well thought out 'modern' styles of living are threatening the existence of many of these species and the ecosystems that support them. Thus, uses that enable a biological resource to be used sustainably are to be sought and promoted.

The principal objectives of the CBD, which was developed by an intergovernmental negotiating committee, are the conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits arising from its utilisation. The convention recognises that the key to maintaining biodiversity including medicinal plants depends upon using this diversity in a sustainable manner. The CBD was opened for signature at the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro on 5th June 1992 and it entered into force on 29th December 1993. Currently, there are 177 parties (as at 31st March 2000). The convention makes a comprehensive approach to the conservation and sustainable use of biological resources. It also addresses the issue of bearing the burden and sharing of benefits fairly and equitably between developing and developed countries on one hand, and indigenous and local communities and, and users in modern sector on the other.

Nigeria signed to the CBD in 1992 and ratified it in 1994. Therefore, as a nation, she is obliged to contribute to the convention's objectives through the conservation and sustainable use of biological resources that abound within her territory. Nigeria is traditionally known to be a rich source of medicinal and aromatic plants. For example Calabar bean, the only natural source of the alkaloid physostigmine, was used as an "Ordeal Poison" in trial of wrong doings many years ago. Many of the medicinal plant species found in all the ecosystems in Nigeria have been subjected to over exploitation and poor management. Many Nigerians can testify that they have benefited from herbal medicine in one way or the other. Furthermore, several medicinal plants have been found to play central to the healthcare of some communities, some of them endemic in nature. If they are lost, the world will lose biodiversity of significant heritage and traditional healthcare in our local

communities will be disorganised. The issues of sustainability and ownership are therefore very pertinent when considering the incorporation of herbal medicine into the national healthcare strategy.

Herbal Medicine

Herbal medicine is part of traditional medicine, in which indigenous plants and materials are utilized for preventive and therapeutic purposes. Available records show that over 80% of the registered Traditional Medicine practitioners make use of leaves, roots and bark of trees of medicinal plants in various forms. Thus, even though there is more involved in African traditional medicines than just herbal remedies, medicinal plants may be regarded as the mainstay of traditional medicine. The WHO (1991) defined herbal medicine as finished, labeled medicinal products that contain as active ingredients aerial or underground parts of plants, or other plant materials, or combinations thereof, whether in the crude state or as plant preparations. Plant material includes juices, gums, fatty oils, essential oils and any other substances of this nature. Herbal medicines may contain excipients in addition to the active ingredients. Herbal medicines may contain by tradition, natural organic or inorganic ingredients which are not of plant origin. However, medicines containing plant material combined with chemically defined active substances, including chemically defined, isolated constituents of plants are not considered to be herbal medicines. The World Health Organization estimates that as much as 80 percent of the world's population, especially those living in tropical countries rely almost exclusively on herbal products as the main form of medication.

Indeed, for millions of Africans, traditional healers are their only contact with medicine of any kind particularly in the rural areas where hospitals are few and doctors are rare. Majority of our people depends on the treatment given by traditional healers, in whom they have great confidence. It is most likely that they will continue to depend on these healers, for a long while. Perhaps the theme, "Strategies to Strengthen the Utilisation of Medicinal and Aromatic Plants in the National Health Care System", specifically aims at generating the critical knowledge that will enable sustainable development of herbal medicines so that it will contribute more meaningfully to the health sector.

In 1995, the Federal Military Government of Nigeria announced its intention to incorporate traditional medicine into the health care system. This announcement was in line with the declaration of ALMA-ATA in 1978, which provided for inter alia the accommodation of proven traditional remedies in national drug policies and regulatory measures. The desire of Government then, was to maintain and encourage the growth and development of traditional medical practice through co-ordination and control.

The Federal Ministry of Health (FMOH) has prepared a document on the regulation and control of traditional medical practice in Nigeria. Furthermore, the National Agency for Food and Drugs Administration and Control (NAFDAC) has produced a valuable document on the criteria for evaluating the quality, safety and efficacy of herbal products and their registration, in line with the WHO guidelines. Therefore, the policy framework for the development and use of herbal medicines is in place in Nigeria. However, there is a huge gap in the areas of environmental and sustainable use policies as well as the need to incorporate the principles of the CBD article 8(j) into sustainable use policies. The major concern here is in the pattern of use of medicinal plants.

2.0 SUSTAINABLE USE OF MEDICINAL AND AROMATIC PLANTS

Sustainable use as outlined in Articles 2, 10 and 15 of the CBD means the use of components of biological diversity of medicinal plants in a way and at a rate that does not lead to long-term decline of the resources. The convention emphasises the need to maintain the potentials of medicinal plants to meet the needs and aspirations of present and future generation. The concept of sustainability is now seen as the guiding principle for economic and social development, particularly with reference to biological resources. The central idea of sustainability is that of ensuring that whatever action is taken, and however useful it might look at the time, its long-term effects must be assessed and if they are negative in the long run, they must be abandoned. Conversely, action that will have long-term beneficial effects should not be ignored in favour of short-term profitability.

Use of a species is likely to be sustainable if:

- it is compatible with maintaining the ecosystem in which the species is found;
- it does not reduce the future use potential and impair the long-term viability of the species; and
- It does not reduce its future usefulness to humans.

Other important considerations are to avoid any use that is wasteful.

The current trend in the use of medicinal plants in herbal medicine falls short of these requirements and there is no indication that it will get better soon. The major areas of concern in the sustainable utlisation of medicinal and aromatic plants in the national healthcare system are as follows.

2.1 The current practice of herbal medicine:

The major challenge in the utilisation of medicinal and aromatic plants in Nigeria lies in the practice. The mode of practice varies from one community to the other. Plant use also vary: (i) among herbalists and diseases, (ii) among ecological zones, (iii) among plant species, (iv) among plant parts used, (v) with herbal preparations and (vi) between the dry and wet season. Practically every practitioner prepares his own remedies without adequate reference to any formulated universal standards. There is no accredited formal training of practitioners. Most of them are illiterates and there is high level of ignorance and poverty amongst them. They employ low level of technology in the preparation of their products. The practitioners continuously exploit medicinal plant resources in order to get as much cash as possible for their subsistence without thinking of the future. Those of them that collect plants from the field are usually not aware of the harm being done. In some places, herbalists and other users boil their plant medicines using the precious fuelwood collected from the some wild forest and by this practice add more insult to ecological injury. Indeed, herbal medicine practice in Nigeria today is an environmental and health emergency.

There is need for total reorientation. Practitioners must be aware of how plants contribute to life. A sustainable use system should be evolved, which will guarantee that the local people do realize benefits from these medicinal plant resources in such a way that will encourage them to contribute to their conservation.

The basic challenge here is to hasten the transition to sustainable use of medicinal plant resources at the grassroots. We must reduce the number of people involved and improve plant based industrial labour and productivity. Well-trained practitioners of herbal medicine will greatly improve the quality of herbal products and stimulate scientific research into many of our medicinal plants and products.

2.2 Poverty

Most of our herbal practitioners live in the countryside where the standard of living is generally very poor. Poverty and herbal medicine are inter-related. The poor are the ones that are usually prone to diseases. Generally, the rural communities depend entirely on forest resources for their sustenance in terms of food security, income, domestic energy and primary health care. By 1998, about 70% of the Nigerian population were said to live in poverty on less than US $1.0 per day (UNDP 1998). In some communities in Nigeria, up to 80% of household materials, e.g. food, utensils, shelter, furniture etc are derived from medicinal plants. Rural poverty is therefore both a cause and consequence of over-exploitation of natural resources and the resultant degradation of the environment. Provision of appropriate information

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concerning sustainable means of harvesting and on other alternative ways of earning living is extremely important for sustainability.

Some key medicinal plant species have been identified to be central to health care delivery in some communities. There is opportunity to strategically these key medicinal plants for preventive and curative medicines in commercial quantities and in this way enhance the economic status of the rural communities through proper management.

2.3. Perpetual damage to ecosystem and loss of medicinal plant species

Activity that consumes the highest number of species in Nigeria today is herbal medicine. Most medicinal plants are harvested with little or no regard to the future. This is damaging to both species and ecosystems. The damage is especially serious, when bark, roots, seeds, or flowers are removed, since these parts of the plant are essential for their reproduction. The emergence of commercial medicinal plant gatherers in response to urban demand has resulted in indigenous medicinal plants becoming endangered. Considering the population of herbal users and the frequency of usage, significant volume of plant materials is used. Several indigenous species have already been lost because of indiscriminate exploitation, and many more medicinal plants face extinction or severe genetic loss. With a human population of over 121.8 million and a population growth rate of 2.5 - 2.6% per annum, if this population growth rate continues unchecked, the population may double within the next 20 years. As the population grows, demand for herbal medicines and other forest resources will increase, and pressure on these will become greater than ever. Rapid increase in population and rising consumption could lead to over exploitation to meet basic needs with irreversible consequences. Presently, there is little or no evidence of large-scale cultivation of medicinal plants. Obviously, herbal medical practitioners lack the means or know-how for large-scale cultivation of medicinal plants, but they can manage backyard gardens in their traditional localities. Gene-banks can easily and economically store large amount of seeds of different species and also allow intraspecies variability. Gene-banks are therefore necessary for conserving sufficient diversity of plants and their relatives to ensure that all their potentials are preserved for use in the future.

2.4 Information data bank

Most of the knowledge on the use of medicinal plants is held by the traditional society whose very existence is also under threat. Lack of information on medicinal plant and their use has great consequences sustainable management. Proper and careful scientific documentation will ensure successful exploitation of the medicinal plants and their conservation. I am aware of the efforts made by OAU/STRC in

Western Nigeria, the NIPRD in the FCT, Bauchi and Ondo States, BDCP in Eastern Nigeria and OAU, Ile-Ife. There is need for a national database on medicinal plants and to link up with others internationally. This may be developed through bio-geographic/socio-economic surveys and adoption of existing data base on medicinal plants so as to provide baseline information that is required to understand the values of medicinal plants to the communities. There is an urgent need for information network on medicinal plants. Information gathering, sharing, awareness promotion, and general improvements in communication between practitioners and other interest groups are vital for sustainable utilisation of herbal medicines.

2.5 Research and Development (R&D)

In order to improve on the general acceptability of herbal medicines and provide it some scientific validity, much R&D work is needed to standardize the nomenclature, collection, extraction, process, formulation procedures, quality, safety, dosage, indications, contra-indications etc. R&D institutions can generate appropriate knowledge and add value to our medicinal plant resources locally. The major drawback in R&D is low funding. Hardly does R&D funds exceed 1% of the GDP in developing countries. Between 2 – 4% of GDP is directed to R&D in the industrialized countries. If we add value to our medicinal plants domestically and build technical capacity for improving the resources, herbal medicine could become an important component of our national economic development strategy. Strengthened capacity, will in turn, allow us to enter into more profitable partnerships with technology-intensive industries. By adding value to medicinal plants, the issues of poverty alleviation, economic and social empowerment, capacity building through training and infrastructure development, improvement of quality of life, improved food security, etc, will be addressed. It is therefore absolutely necessary to establish local SMEs that would add value to medicinal plant products, create jobs, reduce unemployment, and encourage documentation of herbal medicines.

2.6 Biotechnology

Plants are important sources of novel genes that possess valuable medicinal properties. Biotechnology (Genetic engineering; DNA technology; gene splicing) and cell culture are opening new frontiers for the sustainable utilization of medicinal plants. The technique is widely employed in the improvement of plant varieties, and to make or modify products.

Clonal micro-propagation of plants through tissue culture, protoplast fusion, embryo transfer and cryopreservation techniques contribute to genetic improvement of the plants and to conservation of valuable germ plasm. Advancement in biotechnology

and conservation will lead to the establishment of local industries that will add value to domestic products, create jobs, reduce unemployment, reduce import expenditure and generate foreign exchange. It will contribute significantly to the poverty alleviation agenda of our government. There is the need to strengthen our indigenous capacity in biotechnology for sustainable development and use of herbal medicines.

2.0 OWNERSHIP ISSUES

Historically, unimproved genetic and biochemical resources were regarded as the common heritage of humankind, freely accessible by anyone. Developing countries have long been frustrated with this system that labels their resources as "Ownerless" but then establishes private property rights for improved products based on those resources. Interestingly, in Nigeria, the Patent and Design Act of 1970, Merchandise Marks Act of 1958 and the trade Marks Act of 1965, and the National Office of Industrial Property Decree No. 70, 1979 do not contain any specific provisions regarding traditional knowledge or community knowledge.

It is often argued that IPR should be modified in order to internalize the cost of biodiversity loss and management and to ensure that the source countries as custodians, receive more of the economic returns from its development. As a supplement to these property rights, formal and informal contracts have proven to be a more promising avenue for ensuring just compensation for traditional medical knowledge. Therefore, if extending intellectual property rights to unimproved genetic resources fails to capture benefits from the use of medicinal plant resources, contract agreements, and access restrictions and the promotion of value-added industries would. In the process of adopting existing technology and developing new ones for herbal medicine development, R&D institutions should exploit the intellectual property system to make their tasks easier and the discovery less expensive.

There are basically three types of ownership issues (That are relevant to our present discussion) that most directly impact on CBD and access/benefit sharing arrangements viz.:

a) Ownership with respect to "access", i.e. the ability to enter and undertake prospecting or specimen collection activities
b) Ownership with regard to genetic resources i.e. the information
c) IPR with regard to intangible discoveries arising out of use of the genetic material.

3.1 Intellectual Property Rights (IPR)

The most useful and generally utilized form of intellectual property protection for the products and processes in industry is the one provided by the general patent law through patents. Approximately 70 - 80% of the world's store of proven, viable and directly useful technologies are contained in patent documents. Patent documents are therefore important sources of essential technological information. The patent system will continue to be the most important tool for strategic development and should be utilized for herbal medicine development. Patent rights will stimulate the utilization of indigenous knowledge and serve as instruments for licensing of process and products nationally and internationally (Olembo and Sese, 1997).

Article 16.2 stipulates that access to technologies shall be subject to the protection of intellectual property rights. Although this paragraph does not discriminate between individual or community rights holders, it has been taken to apply to private rights held mostly by corporate interests. The community management system has always allowed reward for labour input. Any charge for the biomass embodying biodiversity on a unit weight or volume basis, or any monetary charge made for the technology on a piece of hardware (an implement) basis is for paying for the labour used for production, not for innovation, and fits in well with the community system. But, trying to charge for the community's intellectual achievement or innovation is fraught with difficulties. These include, among others:

a. The problems of identifying the beneficiaries;
b. If the community as a whole is to be the beneficiary, the following problems arise:
   - Are all individuals in any part of the world who originated from the community or communities in question entitled to the benefits?
   - If so, will the community have the organizational and the technical capacities for its additional task of ensuring the inclusion of all beneficiaries?
c. If the community is to act as a single legal individual in direct competition with individual and corporate Northern entities, additional problems arise:
   - Raising in hard currency the money required to register patents (it is estimated at about 10 – 20 thousand dollars for application only and requires annual payments of additional amounts);
   - Deploying the personnel and managing the global industrial espionage system that would be required to prevent unauthorized use of the patented technology, and affording this financially in hard currency. (It should perhaps be noted that IPRs are now used in the North to control markets, and preventing unauthorized use of a patent

usually costs more than the royalties it can fetch are. It is estimated that, on average, maintaining a patent for its lifetime in the US costs about US $250,000);

- Dealing with the near certain private patents on roughly the same technology and/or biodiversity which modify the community technology only a little (e.g. substituting extraction procedure with a different solvent.

These and many other problems arise because we are trying to force one system to run entirely under the norms of another. There is need for new innovative arrangements instead of the old fashioned approach that is hardly flexible enough to accommodate peoples wishes.

3.2 Access to indigenous knowledge and technology

The most promising immediate opportunities for capturing greater benefits from medicinal plant biodiversity involve access restrictions, contracts, and local value-added industries. National legislation regulating medicinal plant collecting activities will provide a more formal mechanism for ensuring that the rights of local communities are respected. Collecting permits should be mandatory to collectors and prior informed consent should be obtained before collection begins. The terms by which access would be given to land or to local knowledge must be properly negotiated.

Article (8j) of the CBD provides that subject to national legislation, the "knowledge, innovations and practices"; in other words, knowledge and technologies of indigenous and local communities shall be respected, preserved and maintained. Access to this knowledge and technologies shall be obtained with the prior informed consent and involvement of the communities. The Conference of the Parties to the CBD, held in Bratislava May 1998, ruled that national law could legally recognize Community Intellectual Rights.

The Organization of African Unity (OAU) at its 34th Summit in Ouagadougou in 1998 endorsed a model law on Community Rights and Access to Biological Resources prepared by the OAU Scientific, Technical and Research Commission, and the Government of Ethiopia. The Summit passed a resolution urging African countries to make their respective national laws based on the model law.

The main elements of Community Rights in the model law are the following. They have rights to:

- The protection in perpetuity (for all time) of the biological resources in their areas, their knowledge and technologies;
- Grant access only after they have been given full information and weighed it in advance of granting their consent. This is referred to as prior informed consent – PIC;
- Refuse access when they want to, and to restrict access when they feel that giving it in full could affect them negatively;
- Develop, keep, use, exchange, sell or share biological resources without any interference by governments, or private natural or legal persons who claim IPR protection; and
- Obtain at least 50% of share of benefits obtained from any commercial use of the biological resources in their areas, or benefits obtained from their knowledge and/or technologies.

Regardless of how they are characterized (license, permit, contract, etc) genetic-resource access arrangements, essentially contractual in nature. As such, contractual negotiations and principles (including the concepts of prior informed consent and mutually agreed terms), form the basis for many (perhaps most) current legislative, policy and strategy documents and principles relating to access.

3.3 Benefit Sharing and Genetic Resources:

The Convention on Biological Diversity assumes that when a state allows access to a sample of genetic resources, it is, in return, entitled to insist on a number of benefits. Research activities on the genetic resources it provides have to be done in its territory to help it build capacity (Article 15, paragraph 6). All the information generated by research on that genetic resource must be repatriate (Article 17, paragraph 2). Any biotechnology applied on the genetic resource must be made accessible to its source country (Article 16, paragraph 3). A fair and equitable share of the benefits accruing from the use, including from commercial gains, of the genetic resource must also be given to the local community or communities and the State from where it was taken (Article 15, Paragraph 7). But all this is conditional upon mutually agreed terms in the form of a contract (Article 17, paragraph 4). Many of the industrialized countries have been undertaking major expeditions in the South to collect genetic resources even after the CBD came into force.

The real benefit obtained depends on the legislation in each developing country and the trained human resource and infrastructure put in place to enforce the legislation. In most developing countries, neither the legislation nor the systems of enforcement are in place. The industrialized countries other than the Scandinavian and some of the smaller countries of the European Union seem to want the situation to continue

unchanged. For example, when the European Commission adopted a directive on patenting genetically engineered living things; it deleted the requirement for disclosing the country of origin of the genetic resources used in the genetic engineering. This item had been introduced by the European Parliament to help developing countries claim benefits from their genetic resources used by Europe. To make matters worse, the developing countries are late with their legislation. Benefit sharing is therefore, being interpreted, as has been the case with resources in the past, as a one-way flow Northwards.

Under the CBD, the concept of "ownership of genetic resource" is also dicey. Unlike "biological resources" (an all-inclusive concept), the term "genetic resources" refers only to "genetic material *of actual or potential value*". Article 2. It is generally agreed that the "value" of genetic resources, is in encoded genetic *information*, which may be used for a variety of purposes, including pharmaceutical and agricultural products development and research. Thus, the gross mass of the biological material from which genetic information is developed is of insignificant "value" in this context compared to the information itself.

5.0 CONCLUSION

Herbal medical practice needs urgent attention in the area of mass education, training and awareness building. The practitioners need appropriate information on sustainable use of medicinal plants and alternative ways of earning their living.

We need to re-examine our relationship with nature, and to harmonize national activities around environmental protection, sustainable use and conservation of natural resources especially the medicinal plants, so as to develop new economic opportunities. There is general awareness about the efficacy of herbal drugs and a bright future exists for the production of drugs and essential oils from medicinal and aromatic plants. There is opportunity to carry development to the countryside through the development of medicinal plants and related non-wood forest products.

There is need to evolve sustainable use and equitable benefit sharing policies at the national level. Similarly, there is need for access legislation at the national level. This may be the only way to uphold and enforce international sanctions whenever there may be need for it. There is need for another legislation to regulate medicinal plant collecting activities to ensure that the rights of local people are respected.

There is need for information network on medicinal plants to ensure exchange of information and monitoring of emerging trends in herbal medicine development

through data collection and analysis. This will also assist in information sharing and awareness building. We need to develop a national database on medicinal plants and an Herbal Pharmacopoeia.

There is need for national capacity building in the areas of biotechnology, information infrastructure and training of herbalists. It is necessary to develop and include suitable medicinal plant conservation and development programmes into schools curricula.

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IUCN
The World Conservation Union

RECOMMENDATIONS

May 2000

Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity

(Nairobi, Kenya 15-26 May 2000)

Access to Resources and Equitable Sharing of Benefits

(Agenda item 23)

"Fair and equitable sharing of the benefits arising out of the utilisation of genetic resources" is one of the three primary objectives of the Convention. Implementation of this objective has lagged behind the others (biodiversity conservation and sustainable use), probably because it is a new and incompletely understood concept. Within the general principle of benefit sharing are two basic goals:

- promoting equity in the distribution of the benefits from use of genetic resources back to the countries providing those genetic resources; and

- recognising that the financial potential of new scientific developments that utilise genetic resources may provide added incentive for their protection, so long as the benefits are felt by the persons and communities who most directly involved in or affected by conservation and sustainable management those efforts.

The Conference of the Parties began in COP4 to address benefit-sharing issues, and their implementation. In addition to three intersessional activities (the Panel of Experts meeting, ISOC, and the Working Group on Article 8(j)), access and benefit-sharing issues have arisen in SBSTTA4 and 5 and been designated for detailed attention in both COP5 and COP6.

As detailed in Annex 1 to this paper, IUCN calls upon COP5 to consider the following measures when addressing agenda item 23:

Develop a comprehensive approach to address access and benefit-sharing issues

IUCN recommends that COP5, in considering the activities identified by the Secretariat for the continuation of the work of the COP, the Panel of Experts, and the Parties relating to access issues:

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- ✓ adopt and emphasise the ultimate goal of a comprehensive approach and consistency of terminology which can apply in a co-ordinated manner across the full range of "benefit-sharing" issues and activities (as variously described in this paper) – to be addressed in detail by the COP over the next 4 years.

Among the issues that are directly included within the overall concept of benefit-sharing are:

- access to genetic resources for commercial/industrial research and development purposes;
- access to genetic resources for scientific/academic/conservation-related purposes;
- ownership of genetic resources;
- other ownership and tenure issues impacted by access to or limitations on genetic resources;
- intellectual property rights arising out of or connected to the use of genetic resources;
- access to technology for conservation and sustainable development of genetic resources;
- access to the technological discoveries arising out of the use of genetic resources;
- distribution of benefits among Contracting Parties which are the providers of genetic resources (equity among nations);
- distribution of benefits among indigenous and local communities, holders of traditional knowledge, farmers, and other local residents who have been the de facto guardians of global biodiversity (interpersonal equity);
- identification of stakeholder groups and "beneficiaries" of benefit-sharing;
- involvement of stakeholder groups, indigenous and local communities, farmers and other local residents in maintaining and sustainably managing ecosystems and habitats;
- the distribution of monetary and non-monetary benefits, within (and outside) the concept of benefit-sharing; and
- the relationship of cost-sharing as a necessary element of the equity and benefit-sharing concepts as stated in or inferred from the Convention.

Develop guidelines, common understanding, and standards regarding access arrangements

While agreeing with the value of guidelines and other documents to facilitate access arrangements, IUCN believes that these documents must be based on the evaluation of certain information regarding the impact of such arrangements on biodiversity. **Accordingly, IUCN recommends that COP5 request the Panel of Experts to:**

- ✓ evaluate national and regional experience as to whether and in what circumstances access arrangements serve as positive or negative incentives with regard to conservation and sustainable development of biological diversity;
- ✓ focus on the achievements and problems encountered to date by Contracting Parties as they implement the access provisions of the Convention, identifying the steps necessary for implementation;
- ✓ identify the needs of both providers and users (of all affected stakeholder groups) which would be addressed within genetic-resource access guidelines.
- ✓ recommend a mechanism, including the CHM, for collecting and sharing information relevant to the economic and financial components of access to genetic resources, including:
  - the nature and extent of industrial demand for genetic resources,
  - the actual value of genetic resources,
  - the actual value of the non-monetary benefits given under genetic-resource access arrangements, and
  - economic evaluations of the performance of various types of access agreements and financial arrangements that have been in operation for some time.

Continue the work of the Panel of Experts on Access to Genetic Resources

The Panel's efforts, directed at the development of guidelines and common understandings regarding genetic resources access arrangements, are clearly of value in promoting and facilitating access arrangements. **IUCN recommends that the Panel, in continuing its work as proposed by the Secretariat, specifically address and inquire into and respond to the following concerns:**

PIC, MAT, and other guidelines

- whether a harmonised approach to these issues will facilitate the participation of both user and provider of the resources, without unduly limiting the flexibility of implementation of Article 15;

- the responsibilities of all Contracting Parties to use of another country's genetic resources within a Contracting Party is pursuant to PIC and MAT requirements;

- the need to address PIC issues at various levels of governance and civil society, including the most decentralised levels;

- the need for guidance concerning the granting of access to genetic resources in non-commercial scientific and educational contexts;

- consistency of national legislation on access and benefit sharing with existing international obligations.

Ex situ collections

- the particular concerns relating to PIC and MAT in new acquisitions by *ex situ* collections,

- the genetic information derived from specimens in *ex situ* collections prior to the entry into force of the Convention,

- the possibility and impact of proposals for a voluntary multilateral or sectoral program and/or fund under which some part of the benefits derived from the use of genetic resources held in or acquired from *ex situ* collections can be captured and allocated to the countries of origin of the species used.

Develop a system of intellectual property rights

IUCN recommends that COP5:

✓ promptly address the issues of IPR which are relevant to access and benefit-sharing including:

- immediate and extensive evaluation of the impacts that agricultural patents derived from traditional varieties and land races, are having on agricultural biodiversity, traditional agricultural practices, and local communities, and if applicable, the development of a legal mechanism for alleviation of the negative impact of agricultural patents derived from traditional agricultural varieties on farmers utilising traditional agricultural practices, which does not compromise the IPR of the developer of the patented variety or process;

- based on an assessment of the relationship of IPRs to access and benefit sharing provisions, the development of guidelines or best practices for achieving equitable benefit-sharing through the use of IPR;

- a *sui generis* option, for the protection of traditionally developed and maintained agricultural varieties;

- promotion of the creation of a *sui generis* system to address and protect traditional knowledge, innovations and practices;

- a mechanism for registration of traditionally developed varieties, and traditional knowledge, innovations and practices, to further the equitable sharing of benefits arising from the use of such commodities;

- integration of the particular issues and concerns of equitable benefit-sharing under CBD into the direct application national IPR legislation;

- further use and evaluation of instruments such as know-how agreements, trade secrets, petty patents and contractual arrangements as a means to protect indigenous and local knowledge, innovations and practices associated with or based on genetic resources.

Build capacity

IUCN recommends that COP5, in its instructions to the GEF regarding the four priority areas identified by the Secretariat for capacity building with regard to Article 15 and other access and benefit-sharing issues, should give special attention to:

✓ building capacity within individual Contracting Parties for executing participatory national planning processes to support implementation of the Convention's access provisions through among other things national strategies and appropriate legislation;

✓ the development of national strategies to guide the adoption of access measures, including appropriate legislation, in individual Contracting Parties;

✓ expansion of capacity within resource-provider Parties generally, to develop innovative approaches to access legislation and institutions, which respond to particular national needs and conditions, and which provide an interface between the local administrative structures and the requirements of resource users;

- ✓ the development of capacity for negotiating MATs within source countries and particularly for participation in the process by the ultimate providers of genetic resources, such as indigenous and local communities;
- ✓ increasing within resource-provider Parties the capacity to negotiate access agreements (prospecting license memoranda, contracts, covenants, memoranda of understanding, etc.);
- ✓ initiating an education/awareness campaign on the Convention's access provisions for key stakeholder groups, including industry; and
- ✓ building domestic capacity within resource-provider Parties to perform effective technological evaluation and oversight with regard to access arrangements.

Recommendations to the Parties

In addition to the foregoing, IUCN offers the following suggestions regarding certain aspects of national legislation and implementation concerning benefit-sharing issues.

In the authorization of national focal points, "who will be responsible for access and benefit-sharing arrangements" within their respective jurisdictions, IUCN urges COP5:

- ✓ to advise the Parties to ensure that that the role and authority of national focal points is carefully specified. While it is important to facilitate the establishment of access arrangements, care must be taken to ensure that appropriate controls on the creation of such arrangements cannot be circumvented.

In addition, IUCN urges COP5

- ✓ to consider mechanisms for developing synergies among the multilateral environmental agreements, through coordination among the national focal points and other designated national representatives under the various MEAs within each country and/or each region.
- ✓ to advise Parties that national strategies and legislation regarding genetic-resource access should include a requirement of periodic, multidisciplinary evaluation of the effects of access policies and the impact of legislation and the actions taken under it in achieving CBD objectives.

Consolidation of the Work on Access (COP4 and COP5) with Benefit-Sharing (COP6)

As a final comment, IUCN reiterates the recommendation that the COP and the Parties recognise the integrated nature of access issues with the larger framework of benefit-sharing due to be addressed in COP6.

The basic concepts underlying the work of the Conference of the Parties in the area of access to genetic resources, and may fill an important role in the broader context of benefit sharing.

Accordingly, it is essential to begin to clarify some of the conceptual ambiguities common to these issues in regard to critical concepts, which have arisen in the course of the first 8 years of the evolution of the CBD.

IUCN recommends that particular attention should be given to the relationships of the various components of benefit sharing (listed above), and the critical underlying definitional issues that may affect these relationships, including

- ✓ the ownership of genetic resources;
- ✓ the definition of the term "genetic resources" and of activities utilising them
- ✓ the broadening of the use of the terms "access" and "benefit-sharing," beyond the limit of Article 15 (benefits from the use of genetic resources) to a broad assortment of kinds of benefits and principles.

ANNEX 1. BACKGROUND PAPER ON ACCESS TO RESOURCES AND EQUITABLE SHARING OF BENEFITS

OVERVIEW

The Convention on Biological Diversity identifies "fair and equitable sharing of the benefits arising out of the utilization of genetic resources" (a concept that specifically includes the issue of access to those resources) as one of its three primary objectives, along with biodiversity conservation and sustainable use. (CBD, Art. 1.) This provision has been cited as "an historic commitment" by the Contracting Parties both to:

- promoting equity in the distribution of the benefits from use of genetic resources back to the countries providing those genetic resources, and

- recognizing that the financial potential of new scientific developments that utilize genetic resources may provide added incentive for their protection, so long as the benefits are felt by the persons and communities who most directly involved in or affected by conservation and sustainable management those efforts.

Owing to the innovative nature of these concepts, however, actual progress in the areas of access and benefit-sharing has lagged far behind the other two objectives. Recognizing the need to develop a clearer understanding of these concepts, the Conference of the Parties has demonstrated a high level of interest and concern regarding access and benefit sharing, in the decisions of COP4, and in plans for COP5 and COP6.

In COP4 and the years that followed, the Parties to the Convention have been very active on access and benefit-sharing issues, both individually and collectively. Individual progress by members has focused primarily on the development and implementation of national policies, strategies and legislation addressing various aspects of access and benefit sharing. Collective activity has been undertaken both through regional action and through the inter-sessional activities mandated by COP4.

National Action

Up to now, action and legislation in the areas of access and benefit-sharing has focused, nearly exclusively, on Article 15 of CBD and the facilitation of private-sector and developed-country access to genetic resources for commercial and research purposes. Within this context, measurable achievements concerning access/benefit-sharing issues have been limited by an array of controversial issues, relating to State sovereignty; economic development; traditional, local and indigenous communities; scientific research; genetic-resource-based industries; intellectual property rights; definitional issues; and equity.

Without waiting for international consensus in any of these areas, over 40 Contracting Parties have addressed some of the practical necessities of genetic resources access, either by adopting new legal frameworks relating to the mechanisms for access (particularly mechanisms for prior informed consent and mutually agreed terms), or by modifying existing legislation on biological resources to appertain to these issues. Nearly all of these legislative and policy innovations have been adopted within the last 4-5 years, and are specific outgrowths of Article 15. Often highly innovative, many of these legal and strategic documents and frameworks have been developed through consultation and participatory decision-making and legislative/policy processes that cut across a wide range of interested parties and groups, including indigenous and local communities.

The bulk of this strategic, planning and legislative activity has been centred in resource-provider Parties (primarily, but not exclusively, developing countries), and is designed to protect and to ensure their financial and other interests and prospects with respect to this potentially valuable category of resources. All of this activity is clearly indicative of a high level of interest and concern regarding access and benefit sharing. It may also be a barometer of the volume of genetic-resource-oriented activities around the world.

International action

International action in this area has also been extensive, particularly in very recent years, and has included groundbreaking regional agreements, as well as the work of the CBD COP. Genetic-resource access and benefit-sharing issues were tabled for discussion in COP4, where several significant decisions were taken, including the designation of these issues for detailed attention over the next several years.

In decision IV/16, COP4 decided to hold an Inter-sessional Meeting on the Operations of the Convention, addressing numerou issues under the Convention, including specifically, access to genetic resources, benefit-sharing, *ex situ* collections, and the relationship between the CBD and intellectual property rights and the TRIPs Agreement.

One mandate given to and fulfilled by the Inter-sessional Meeting was to recommend the composition and agenda for a Panel of Experts on Access and Benefit Sharing, established by COP4 (Decision IV/8.)

An important related issue – the protection of the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles – was addressed in decision IV/9, under which an Inter-sessional Working Group on the Implementation of Article 8(j) and related Provisions of the Convention was convened. This meeting is underway at the time o this writing (March, 2000, in Seville, Spain.)

Most important, in its decision IV/16, Annex II, COP4 identified "access to genetic resources" as an item for in-depth discussio in COP5, and "benefit-sharing" to receive the same attention in COP6. Given the critical nature of the linkage between these two concepts, and the extent to which both concepts directly influence numerous other critical concepts and activities under the CBD, it is important for the Parties to develop a consistent framework of understanding to facilitate collective action and decision-making with regard to these critical issues over the coming years.

ACCESS TO GENETIC RESOURCES: IMPLEMENTATION OF ARTICLE 15

In Bratislava, COP4 decided to establish a Panel of Experts on Access and Benefit-Sharing who were charged with "development of a common understanding of the basic concepts, and explore all options for access and benefit-sharing on mutually agreed terms including guiding principles, guidelines, and codes of best practices for access and benefit-sharing arrangements." (Decision IV/8. The modalities of this process were set in the Inter-sessional Meeting on the Operations of the Convention in Montreal. (Report of the Inter-Sessional Meeting, Recommendation 2, para. 3, *and see* COP4 Decision IV/16.)) The Panel of Experts met in Costa Rica in October, 1999, and produced a number of conclusions which are reported to COP5 ir Document 8. Additional critical activities in this thematic area include the recommendations of the Inter-sessional Meeting on the Operations of the Convention, with regard to *ex parte* collections, and intellectual property rights, and the deliberations of the *Ad Hoc* Working Group on Article 8(j).

IUCN believes that these activities have begun a process that will be essential to the ultimate resolution of the numerous issues of global, regional, national and subnational strategy, policy, law and interpretation that continue to limit efforts to implement Article 15, and to achieve the benefit-sharing objective and mandate of Article 1 of the CBD.

Accordingly, IUCN recommends that COP5, in mandating the continuation of the work of the COP, the Panel of Experts and the Parties concerning access issues:

- ✓ emphasize the ultimate goal of consistency of terminology and approach which can apply in a coordinated manner across the full range of "benefit-sharing" issues and activities, as variously described in this paper.

Contractual Principles Underlying Access Arrangements

Regardless of how they are characterized (license, permit, contract, etc.) genetic-resource access arrangements are, at base, essentially contractual in nature. As such, contractual negotiations and principles (including the concepts of prior informed consent and mutually agreed terms) form the basis for many (perhaps most) current legislative, policy and strategy documents and principles relating to access. Although concluding that it would be premature to attempt to develop a set of "principles" with regard to access arrangements, the Panel recognized that there are already many bases of "common understanding" within this area, as well as many existing documents that could serve as sources of interim guidance for the parties, particularly with regard to prior informed consent.

In its initial deliberations, the Panel directed primary attention to those actions and decisions which are believed to facilitating use of genetic resources, by creating a hospitable business environment for parties who might potentially wish to seek access to a provider's genetic resources. For example, parties are encouraged to develop "legal certainty and clarity" which will facilitate access and use of genetic resources, by giving potential resource users confidence concerning the extent of restrictions that will be imposed upon them. Similarly, the Panel recommended, in relation to mutually agreed terms, that each country "seek to minimize transaction costs."

In a growing number of countries, the adoption of access-related legislation, strategic documents, and even new governmental or non-governmental agencies, occurs in connection with a specific transactional situation. Legislative and other documents and commitments have frequently been developed concurrently with, as a result of, or in specific expectation of negotiations with private companies or other governments seeking to acquire specific rights to prospect for, collect and use genetic and other resources for commercial research and product development.

IUCN recognizes and supports the principle that fostering appropriately compensated, environmentally beneficial use of biodiversity, when coupled with equitable sharing of the benefits of such uses, may have a net positive effect on the conservation of biodiversity, but cautions that not all existing arrangements and recent experiences in the area of genetic resource access policy, strategy and legislation may have achieved such effects.

Accordingly, IUCN recommends that COP5 request the Panel of Experts to:

- evaluate national and regional experience as to whether and in what circumstances access arrangements serve as positive or negative incentives with regard to conservation and sustainable development of biological diversity;

- focus on the achievements and problems encountered to date by Contracting Parties as they implement the access provisions of the Convention, identifying the steps necessary for implementation;

- identify the needs of both providers and users (of all affected stakeholder groups) which would be addressed within genetic-resource access guidelines.

IUCN also urges COP5 to advise Parties that:

- ✓ national strategies and legislation regarding genetic-resource access should include a requirement of periodic, multidisciplinary evaluation of the effects of access policies and the impact of legislation and the actions taken under it in achieving CBD objectives.

Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT)

Particular and immediate attention is needed for the development of parameters for PIC and MAT. This necessity is recognized from both sides of the genetic-resource access transaction.

For supplier countries, a serious concern is the lack of technical, institutional or financial capacity to require, evaluate and enforce the technical and procedural requirements embodied by the concepts of PIC and MAT. Although they bear the primary responsibility under the Convention to implement these requirements, these countries may not be in a position to do so, or to evaluate the sufficiency of these activities.

By contrast, the responsibilities of other Contracting Parties are unclear with regard to genetic resources from other Parties that are being used within their jurisdiction. Legislation exists in a few countries that is designed to ensure that users of another Party's genetic resources obtained those resources in compliance with relevant PIC and MAT requirements. These provisions have been incompletely implemented due to difficulties in confirming compliance. The lack of a harmonized approach to PIC, MAT, and other matters may increase the costs and difficulties of potential users of genetic resources seeking to utilize or study samples in their own countries, particularly in those countries whose laws now require proof of compliance with access requirements of the country of origin of the samples.

These strictures often have greatest impact on non-commercial researchers and scientists. Access requirements under CBD were intended to foster rather than limit scientific inquiry into biodiversity and its genetic resources. By increasing the potential for countries to share in the commercial value of new discoveries, it was hoped that such innovation and inquiry would be fostered. At the same time, the addition of access/benefit-sharing legislation and requirements has, in many cases, had a

chilling effect on non-commercial scientific research, which is often conducted on relatively minimal funding, and cannot afforc the costs of compliance with access/benefit-sharing requirements under new policies.

Moreover, in many countries, both the process of negotiation of MATs and the authorities designated for implementing PIC are greatly decentralized. Increasingly, PIC processes, and even MAT negotiations occur on many different governmental and social levels, from the central government to meetings with to indigenous persons and local communities living traditionally, and are contingent on satisfactory resolution at all levels.

The Panel of Experts identified a number of issues of legislative development that should be understood in order for the Parties to facilitate the creation of genetic resource access arrangements, including a number of areas in which additional research is necessary prior to the commencement of the process of developing the recommended guidelines for PIC and MAT.

In addressing these issues, IUCN recommends that COP5 request the Panel of Experts to:

- specifically consider whether a harmonized approach to the implementation and documentation of prior informed consent procedures can be developed that will facilitate compliance with these requirements from the perspective of both user and provider, without unduly limiting the flexibility of implementation of Article 15;

- consider a more equitable distribution of the responsibilities for implementing the Convention's access provisions, in particular, establishing clearly the responsibilities of all Contracting Parties to ensure that, when legal and natural persons within their jurisdiction use genetic resources provided from another Contracting Party, this use is pursuant to PIC and MATs;

- address the issue of PIC at different levels of governance and civil society, recognizing the difference in the role and objectives of PIC at each such level;

- provide guidance concerning the granting of access to genetic resources in non-commercial scientific and educational contexts;

- ensure that national legislation on access and benefit-sharing is consistent with existing international obligations and does not restrict or undermine Parties' positions in ongoing international negotiations and foreclose options, including, possibly, the option of adhering to future agreements such as plant genetic resources for food and agriculture (as currently being negotiated within FAO.)

Intellectual Property Rights IPRs

In general, the integration of IPR regimes with the CBD faces many difficulties borne of their respective mandates. In the more specific context of Article 15,[1] however, integration with TRIPs appears to offer few additional difficulties, in light of the similarity of objectives. Specifically, according to TRIPs Article 7 (*Objectives*), the protection and enforcement of IPRs should, promote technological innovation and the transfer and dissemination of technology, "to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations." These objectives seem to dovetail with the genetic-resource access and benefit-sharing objectives of Article 15.

This appearance of complementarity of objective between the two provisions may be deceptive, however. The recent seed-saver lawsuits, offer cases in point. In some of these situations, the patent rights being asserted have arisen out of direct, authorized access to biological resources of a producer country. The subsequent controversies over producers' and users' respective rights with regard to the products of this access underscore the manner in which IPR relating to genetic resources may be injurious to the objectives that Article 15 seeks to achieve. In particular, the concept of benefit-sharing as exemplified in these cases evidences a relatively deep divide between the two over the meaning of "benefit" and the manner and extent to which it is shared.

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[1] These recommendations will not address the issues of access to technology under the CBD, sanitary and phytosanitary standards in international trade, and other matters not directly within the scope of the basic concepts of access to genetic resources under Article 15. In so doing, IUCN does not which to give the impression that these issues are unimportant, and stresses that these questions should be fully addressed under other relevant thematic areas and agenda items (*see, e.g.,* agenda item 17.3 relating to alien invasive species.)

Agricultural biodiversity and its preservation is a critical component of the CBD. To a large extent the remaining diversity of agricultural species is both a product and a component of traditional methods of variety development and maintenance. Rigorous application of IPRs in this area may have the effect of compromising the rights and abilities of farmers to engage in these traditional practices. Moreover, assertion of patent rights against traditional farmers may have the effect of catalyzing opposition to the wider use of patents and other IP protection mechanisms with regard to plant varieties and other biological developments. By contrast, under current law, failure to take action to protect one's IPRs may seriously compromise the enforceability of those IPRs in other situations.

Beyond these primary intellectual property issues, the application of IPR within the context of Article 15 implementation becomes even less clear. Of particular concern is the relationship between IPR and the knowledge, innovations and practices of local communities, under Article 8(j) – a concept that is both practically and legally connected to the implementation of Article 15. In many instances, applications for access to genetic resources have been directly linked to requests to study or collect traditional knowledge relating to those resources (presumably under Articles 17.2 and 18.4.) In addition, since Article 8(j) contains a mandate for benefit-sharing that is essentially identical to that of Article 1, parallels between the two situations are easily drawn.

Holders of traditional knowledge and traditional agriculturalists, like provider countries (with regard to genetic resources over which they have sovereignty), are justifiably concerned that they have only a limited opportunity to protect or profit from that knowledge or the use of their resources. Similar problems relate to the fact that some such knowledge is widely held by many different communities throughout a region.

Moreover, even if a mechanism is developed which will provide some level of legal protection to holders of traditional knowledge and varieties, a larger problem would remain – enforcement. Unfortunately limits on patentability and protectability of certain resources and indigenous knowledge have not prevented the commercial utilization/exploitation of these commodities. However they may prevent the communities which have maintained and protected them from sharing in the benefits of such use. Recent claims of so-called "bio-piracy" underscore the need for interest holders to be aware of new biology-based patent applications, in order to protect that interest.

The state of technological advancement of the sciences involved in the creation, and patenting (and confirmation of patent information concerning) genetic-resource-based innovations may be preventing some countries from being aware of infringements on their rights with regard to genetic resources over which they have sovereignty. The vigilance with regard to the legal/IPR regimes that is needed to ensure that prevent infringement of protected or protectable knowledge or commodities may be beyond the capability of many countries. For many of the stakeholder groups most directly involved in these issues (traditional agriculturalists, holders of traditional knowledge, and even the government agencies charged with protecting their interests), it would not be possible to maintain the necessary level of awareness of these issues.

IUCN agrees with the Secretariat and the Expert Panel that major gaps remaining with regard to IPR and related issues, including:

- the extent to which IPRs for seeds, plant varieties and/or agrochemicals affect biodiversity (whether positively or negatively.)

- whether and how the precautionary principle may be applied in the IPR context to minimise the risks without (a) being construed as an illegal barrier to trade or (b) foreclosing opportunities for developing countries to use IPR law to enhance their life science and technology capacities.

- whether IPRs hinder or encourage the transfer of private technologies supportive of biodiversity conservation to developing countries.

IUCN believes that, while it is important to undertake further study concerning these issues, undue delay in addressing these issues may compromise the ability to assert these rights, particularly as they might apply to traditional varieties, land races, and traditional knowledge.

Accordingly, IUCN recommends that COP5:

- ✓ address the issues of IPR which are relevant to access and benefit-sharing as expeditiously as possible, giving particular attention to issues concerning the need for:

- immediate and extensive evaluation of the impacts that agricultural patents derived from traditional varieties and land races, are having on agricultural biodiversity, traditional agricultural practices, and local communities, and if applicable, the development of a legal mechanism for alleviation of the negative impact of agricultural patents derived from traditional agricultural varieties on farmers utilizing traditional agricultural practices, which does not compromise the IPR of the developer of the patented variety or process;

- based on an assessment of the relationship of IPRs to access and benefit sharing provisions, the development of guidelines or best practices for achieving equitable benefit sharing through the use of IPR;

- a *sui generis* option, for the protection of traditionally developed and maintained agricultural varieties;

- promotion of the creation of a sui generis system to address and protect traditional knowledge, innovations and practices;

- a mechanism for registration of traditionally developed and maintained agricultural varieties, and traditional knowledge, innovations and practices, to further the equitable sharing of benefits arising from the use of such commodities;

- integration of the particular issues and concerns of equitable benefit-sharing under CBD, into the direct application national IPR legislation;

- further use and evaluation of instruments such as know-how agreements, trade secrets, petty patents and contractual arrangements as a means to protect indigenous and local knowledge, innovations and practices associated with or based on genetic resources.

Ex Situ Collections

Ex situ collections which predate the CBD's entry into force are technically outside the requirements of Article 15, as are collections acquired in accordance with the Convention. As a result, these organizations' transactions in and use of their specimens may not be bound by any obligation even to be accountable for the uses for which specimens may be acquired. In essence, the operations of these collections may lead to complete severance of the countries of origin of a particular species from any equitable share in the benefits derived from utilization of its genetic resources.

As discussed in greater detail below, however, the Convention's overall objective of benefit-sharing suggests that appropriate efforts to re-connect source countries to the benefit-sharing nexus with regard to a particular species would be within the mandate of the CBD. Moreover, the overwhelming majority of *ex situ* collections were established to further objectives essentially identical to those of the CBD – ensuring the conservation and sustainability of as much of the Earth's biodiversity as possible. CBD's benefit-sharing concept is designed to further these objectives, by giving its Parties some additional incentive to conserve and protect its remaining biodiversity.

Last June, the Intersessional Meeting on the Operations of the Convention met to consider matters identified in Decision IV/16, including issues relating to *ex situ* collections that pre-existed the CBD's entry into force, and are not addressed by the CGRFA (FAO Commission on Genetic Resources for Food and Agriculture.) At its close, the Meeting recommended that COP5 continue its "information gathering exercise" through the gathering of voluntary information with regard to these collections and their facilitation of capacity-building, technology development and other activities which, on a sectoral basis might further the principles of access and benefit-sharing. These recommendations have been adopted by the Secretariat,

IUCN recommends that COP5 request the Panel of Experts, in addressing the issue of access and benefit-sharing,

- ✓ focus particular attention on the particular concerns relating to MAT in new acquisitions by ex situ collections, and to the genetic information derived from specimens in *ex situ* collections prior to the entry into force of the Convention, including the possibility and impact of proposals for a voluntary multilateral or sectoral program and/or fund under which some part of the benefits derived from the use of genetic resources held in or acquired from ex situ collections can be captured and allocated to the countries of origin of the species used.

Financial Provisions in Genetic-Resource Access Agreements and Arrangements

Current concerns and lack of knowledge relating to the valuation of genetic resources are relevant to the full range of contractual issues under Article 15. One of the most commonly cited impediments to the conclusion of access agreements is the extent of uncertainties and misconceptions concerning the nature and value of the genetic resources.

Fearing that they may only have one chance to profit from the use of any given species, or the grant of access to their genetic resources in general, provider countries are understandably concerned not to be enter into a contract that will later be found to have undervalued the resource. Political and public pressure, sometimes born of media attention focused on well-publicized profitable discoveries, particularly in the pharmaceutical field, can contribute to this concern, at once urging immediate action, and creating a fear of binding the country to a particular contract or compensation arrangement.

The economic value of "biodiversity prospecting," and the extent of positive benefits from access arrangements is still a subject of debate. As a result, many contracts avoid the issue, by emphasizing non-monetary benefits, which can be committed "up-front," even without certainty concerning the ultimate economic value of any particular species or category. Without discounting the value of these benefits (particularly those such as education, public awareness and the development of self-sustaining institutions, each of which should result in long-term improvement in the source country), their use does not resolve the basic problem of lack of information on valuation.

The comparable limitation from the user side of the transaction is frequently expressed in terms of confidentiality and trade secrets. Obviously, the most important and valuable benefits from the access to genetic resources are (1) the information obtained, and (2) the patent or intellectual property right relating to uses of that information. Resource users are reluctant to share these most valuable results of access, particularly at the contractual stage in which the actual products and values are still speculative.

Resource provider governments are chary of entering into contracts with multinational corporations and other entities which seem to possess superior negotiating strengths, and more sophisticated understandings of the true import of the contractual provisions being proposed. In light of the importance of the issue, governments are increasingly uncomfortable with contracts that specify complex royalty schemes based on incompletely understood scientific developmental concepts (for example, whether the ultimate product is a "direct or a synthesized isolate" of the original extract), and unwilling to rely on user explanations of the import of such provisions.

IUCN recognizes that there is a present need for additional information regarding the economic valuation of genetic resources.

Accordingly, IUCN recommends that COP5 initiate a process (through the CHM or otherwise) for the development of a mechanism for sharing information relevant to:

- the nature and extent of industrial demand for genetic resources,
- the actual value of genetic resources,
- the actual value of the non-monetary benefits given under genetic-resource access arrangements, and
- economic evaluations of the performance of various types of access agreements and financial arrangements that have been in operation for some time.

Informational Development and Capacity Building

Ultimately, the success of genetic-resource access programs is integrally connected to the development of several elements -- effective strategy, plans and legislation, and the effective direction and oversight of their implementation. At present fewer than 50 Contracting Parties have adopted any type of genetic-resource access program encompassing these elements. Of these Parties, only a few are economically developed countries. As a result, even international experts in this thematic area possess relatively limited understanding, experience and capacity with regard to the implementation of Article 15.

Particular concerns about national and sub-national capacity to implement Article 15 relate to the lack of capacity to participate effectively in negotiations which are both financially and technically sophisticated, and the need for improved legislative capacity to address issues arising in the evolution of this area of law, and administrative capacity to oversee, administer and enforce such access arrangements.

In one sense, the development of guidelines and principles relating to these contractual arrangements has been recognized as a mechanism both for clarifying the special concepts applicable under Article 15, and for creating a "level playing field" in which negotiations can go forward with less concern that unique or unfamiliar legal principles may later affect the provider country in unexpected ways.

The Secretariat's report identifies four particular areas of capacity-building: information-management skills (including those related to assessment and inventory), contract negotiation skills, legal drafting skills, and development of sui generis IP regimes. IUCN believes that, in order to address these broad areas of concern, capacity-building must be supported by and complement the general processes and activities undertaken by each of the Contracting Parties, based on the strategic, planning and legislative activities which are recommended in the Secretariat's report and other documents, as well as other such responsibilities which have been recommended by this body in the past.

Accordingly, IUCN believes that COP5, in its recommendations guidance to the GEF regarding the four priority areas identified by the Secretariat for capacity building with regard to the implementation of Article 15 and other access and benefit-sharing issues, should give special attention to:

- ✓ building capacity within individual Contracting Parties for executing participatory national planning processes to support implementation of the Convention's access provisions through among other things national strategies and appropriate legislation;
- ✓ the development of national strategies to guide the adoption of access measures, including appropriate legislation, in individual Contracting Parties;
- ✓ expansion of capacity within resource-provider Parties generally, to develop innovative approaches to access legislation and institutions, which respond to particular national needs and conditions, and which provide an interface between the local administrative structures and the requirements of resource users;
- ✓ the development of capacity for negotiating MATs within source countries and particularly for participation in the process by the ultimate providers of genetic resources, such as indigenous and local communities;
- ✓ increasing within resource-provider Parties the capacity to negotiate access agreements (prospecting license memoranda, contracts, covenants, memoranda of understanding, etc.);
- ✓ initiating an education/awareness campaign on the Convention's access provisions for key stakeholder groups, including industry.
- ✓ building domestic capacity within resource-provider Parties to perform effective technological evaluation and oversight with regard to access arrangements.

CLARIFYING THE LINKAGES BETWEEN ACCESS UNDER ARTICLE 15 AND THE CBD'S BENEFIT-SHARING OBJECTIVES

In designating "access to genetic resources" as an area for in-depth discussion by COP5 and "benefit-sharing" for COP6 (decision IV/16, Annex II), the Conference of the Parties has provided itself with an opportunity, and perhaps a mandate, over the coming four years, to address the issues of access and benefit-sharing in terms of their significance to the overall objectives and operation of the Convention. For this reason, is important to begin now to address and consider the concepts of equity and benefit-sharing and to develop a consistent framework of understanding the nature of their relationship to the genetic-resource access provisions of Article 15, and of their broader implications as stated in and inferred from other provisions of the CBD.

In Article 1, the CBD identifies the "fair and equitable sharing of the benefits arising out of the utilization of genetic resources" as one of its three overarching objectives. Article 1's provisions clearly indicate that this commitment to benefit-sharing "includes" numerous other issues relating to genetic resources, such as access to genetic resources (Article 15), transfer of technology (Article 16), ownership/intellectual property issues, and financing issues.

Since the Convention has entered into force, the concept of benefit-sharing has continued to evolve and develop, but relatively little specific implementation has occurred, except in the context of Article 15.7. While the implementation of the express mandate of Article 15 is clearly an important component of the overall benefit-sharing concept, the development and

implementation of systems for the administration of access policies and the payment of compensation (license fees, access payments, and "non-monetary benefits") to specific provider countries or communities is clearly only a part of the overall benefit-sharing objective.

The concepts of "fairness" and "equity" in this context may suggest the need to consider, within the thematic area of "benefit-sharing" many issues and questions that have not, as yet, been fully addressed by the Parties.

IUCN recommends that COP5, acting through the Panel of Experts, and otherwise:

- ✓ begin the process of developing a consistent framework of understanding concerning the relationships of the various components of benefit sharing, and the critical underlying definitional issues that may affect these relationships.

The following are initial examples of areas which must be addressed as part of this process

Ownership of Genetic Resources

One example of an important, but undiscussed issue under the CBD relates to the nature of the concept of "ownership of genetic resources."[2] Unlike "biological resources" (an all-inclusive concept), the term "genetic resources" refers only to "genetic material *of actual or potential value.*" Article 2. It is generally agreed that the "value" of genetic resources, is in the encoded genetic *information*, which may be used for a variety of purposes, including pharmaceutical and agricultural product development and research. Thus, the gross mass of the biological material from which genetic information is developed is of insignificant "value" in this context compared to the information itself.

Comparable situations exist throughout the realms of industrial, commercial and scientific endeavor. Most similar, perhaps, is the burgeoning field of software development, in which the basic programming (the "code") underlying the software system is considered a highly valuable resource, and protected through a complex system of encryption and confidential holding entities. The major difference between these two examples is that, while in the software field, the existing support structure behind protection of intellectual property rights is designed to protect the code (as a trade secret whose value may be lost if the code becomes common property), in the area of genetic resources, all structures are aimed at widening access to and use of this valuable information.

Since the CBD entered into force, It has frequently been stated that "*ownership of genetic resources is a matter of state sovereignty, to be resolved under the laws of the various Contracting Parties.*" This statement ignores the special nature of genetic resources. Specifically, although there is but one set of genetic information for each particular subspecies, species distribution does not respect national boundaries, and subspecies that are substantially similar for these purposes may be found in more than one Contracting Party.

Recent patent filings indicate that, once that genetic information has been acquired by a particular user, it may be patented in a manner that forecloses a full range of uses, beyond the user's particular current application. While this situation suggests a need for further development within patent law, it also demonstrates the need to clarify the concept of ownership of genetic resources, and its relation to the identification of stakeholder groups, the role of regional legal initiatives, and the application of the concept of "equity."[3]

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[2] There are essentially three types of ownership issues that most directly impact on the CBD and access/benefit-sharing arrangements: (1) Ownership or dispositive rights with regard to "access" (*i.e.*, the ability to enter and undertake prospecting or specimen-collection activities), (2) ownership or dispositive rights with regard to the genetic resource (*i.e.*, the information), and (3) intellectual property rights with regard to intangible discoveries arising out of use of the genetic material. The text refers to the second type of ownership.

[3] A similar statement could be made with regard to traditional knowledge, which is often held diffusely by many indigenous and local communities, without regard to national boundaries. Recently after one government authorized researchers to commence a study of medicinal lore of a particular region, several of the affected communities indicated that they would not participate for ethical cultural reasons. Despite this opposition from legitimate holders of the particular traditional knowledge, the study is going forward through interviews with other (non-objecting) communities.

Definition of "Genetic Resources"

Considerable attention and emphasis has generally been laid on the fact that the application of CBD's access and benefit-sharing requirements is generally limited to "genetic resources." For these purposes, the term genetic resources has been defined relatively narrowly ("genetic material of actual or potential value") as has its component term "genetic material" ("plant, animal, microbial. . . [material] containing the functional units of heredity.)

A significant amount of the activity undertaken under the Convention's genetic-resource access provisions, however, does not appear to involve "genetic resources." Several case studies reported in the Clearinghouse Mechanism relate to (1) the study of biological and biochemical properties of particular species, in order to synthesize substances to replicate those properties; (2) the negotiation of access to biological resources which cannot be synthesized for purposes of sustainable commercial use of their extracts; and even (3) programs for the collaborative management of wildlife and other biological resources. Although none of these activities utilizes the species' "functional units of heredity," each clearly evidences an important use of the unique biochemical or other qualities of the species.

Since 1992, significant scientific, technical and social development has occurred with regard to both genetic material and the study and utilization of unique biochemical properties of biodiversity. In light of this evolution, it may be appropriate for the Parties to re-consider in depth the proper interpretation of the "genetic resource" limitations of Articles 1 and 15.

Extension of Benefit-sharing Beyond Genetic Resources

Perhaps the most important development in the CBD has been the evolution of the benefit-sharing concept over the ensuing years. A great many of the outgrowths of this concept have application well beyond the realm of genetic resources. In particular, an express outgrowth of this issue is the application of benefit-sharing language to other discussions of biological resource conservation, sustainable use and development, on many levels, from the relationships among Contracting Parties to the relationships among natural and juridical persons and groups.

Although not specifically included within the benefit-sharing language of Article 1, many of these applications find support among the other provisions of the Convention. Most tellingly, this usage of the concept finds support in the basic underlying purpose of Article 1 and of the convention in general – to promote conservation using sustainable mechanisms (sovereign and domestic rights and interests, as well as the use commercial, economic and contractual approaches.)

For example, the report of SBSTTA5 includes a recommendation on the "Ecosystem Approach" (UNEP/CBD/COP/5/3 at V/10.) This recommendation lists the following as a point of "operational guidance for application of the ecosystem approach":

> *to "promote the fair and equitable access to the benefits derived from the functions of biological diversity in ecosystems and from the use of its components."*

This phrasing was the final product of a lengthy discussion, in which a second concept – "fair and equitable access to the benefits" was also discussed. The extent of this discussion demonstrates the importance and subtlety of some of the unresolved issues relating to concepts of equity and benefit sharing under the Convention.

Although clearly beyond the scope of Articles 1 and 15, and in many instances clearly not related to genetic resources, such uses of the "benefit-sharing" terminology seem well supported by other provisions of the Convention, which seek to assure that biodiversity continues to be available to provider countries and local people on an equitable basis. For example, numerous provisions mandate that activities relating to the use, maintenance and study of biological resources and genetic resources should be undertaken, where possible, in the country of origin of those resources. (*See, e.g.,* Articles 8(m), 9(a), (b), and (e), and 12(a) and (b)). Similarly, provisions such as Article 11 recognise the importance of utilizing positive incentives, as well as contractual and other mechanisms.

Whether it represents an evolution of the benefit-sharing concept, or merely evidences that the terminology (benefit-sharing) has been used in a multiplicity of situations, and taken on a variety of secondary meanings not related to the original use of that term, the precise phrasing is not, perhaps, the most important issue. Rather, this expansion of terminology may have direct bearing on the manner in which the CBD's overall objectives, as well as the benefit-sharing objectives are perceived and applied.

Other Issues

The breadth of the concept of fair and equitable benefit-sharing has been a source of numerous difficulties relating to its implementation. The basic concept appears to include a number of separate, but closely related, issues, including:

- Access to genetic resources for commercial/industrial research and development purposes;
- Access to genetic resources for scientific/academic/conservation-related purposes;
- Ownership of genetic resources;
- Other ownership and tenure issues impacted by access to or limitations on genetic resources;
- Intellectual property rights arising out of or connected to the use of genetic resources;
- Access to technology for conservation and sustainable development of genetic resources;
- Access to the technological discoveries arising out of the use of genetic resources;
- Distribution of benefits among Contracting Parties which are the providers of genetic resources (equity among nations);
- Distribution of benefits among indigenous and local communities, holders of traditional knowledge, farmers, and other local residents who have been the de facto guardians of global biodiversity (interpersonal equity);
- Identification of stakeholder groups and "beneficiaries" of benefit-sharing;
- The relationship of cost-sharing as a necessary element of the equity and benefit-sharing concepts as stated in or inferred from the Convention.
- Involvement of stakeholder groups, indigenous and local communities, farmers and other local residents in maintaining and sustainably managing ecosystems and habitats;
- The distribution of monetary and non-monetary benefits, within the concept of benefit-sharing.

GLOBAL POLICY TRENDS IN COMPLEMENTARY & TRADITIONAL MEDICINE

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NEW LEVELS OF DEMAND

In both industrialised and developing societies, use of complementary and traditional medicine is on the rise.

In 1993 research at Harvard University found that 30 % of Americans were some form of complementary medicine (CM) on a regular basis. In 1998, the same research team reported that this number had increased to 40% of the population (Eisenberg et al., 1998). Research published in The Lancet in 1996 reported that 40 % of Australians were using some form of complementary medicine (MacLennan et al 1996). In April 1999, legislation to establish an Australian Office of Complementary Medicines was announced in Hansard as being warranted since 60% of Australians regularly use some form of complementary medicine. Demand is spiraling at rates that outstrip the capacity of national health policy to keep abreast.

In the US, higher educational level, higher income, and poor health have been found to be predictors of complementary medicine use (Astin, 1998). Americans and Australians typically pay out of pocket for CM services. Americans spend more out of pocket on CM than on all US hospitalisations. Australians spend more on CM than on all prescription drugs. Women have been found to be the majority of CM users in the US, the UK and Australia

TRADITIONAL MEDICINE USE IN DEVELOPING COUNTRIES

Traditional health care (THC) in non-industrialised countries remains the source of everyday health care for the majority of the population of most countries. The World Health Organisation has consistently estimated that between 60-80% of the population of these countries rely on THC for their basic health care needs - sometimes on its own and sometimes in conjunction with modern medical care. Studies show that demand is on the increase in many countries.

Contributing to a trend towards increased traditional medicine utilization in non-industrialized countries is the reality that pharmaceutical drugs:

(I) are available only intermittently,
(II) are expensive - often unaffordable,
(III) are variable in their effect (e.g. increasing resistance of bacteria and of the malaria parasite to conventional treatments).

Cultural familiarity, local availability and affordability combine with consumer satisfaction with outcomes to ensure that traditional medicine will continue to have an important role into the 21st century

POLICY TRENDS

Faced with growing demand for complementary medicine in the industrialised countries and in many Caribbean countries, and continued reliance on traditional medicine in non-industrialised countries, Commonwealth Health Ministers at the 12th Commonwealth Health Ministers meeting, held in Barbados in November 1998, established a working group to develop an action plan to review policy and development in TH/CM. The review will be designed to promote and integrate TH/CM into national health services as an essential part of the agenda for health sector reform in Commonwealth countries (Nelson 1998).

The Global Initiative For Traditional Systems (GIFTS) of Health was appointed to establish and co-ordinate the Commonwealth-wide Working Group, with initial membership of 14 countries.

The Working Group will oversee a comprehensive scoping exercise of the following areas:

- Regulation and safety
- Research. recording the traditional health heritage; efficacy, effectiveness and cost - effectiveness; inventories of medicinal plants; pharmacopoeia; conservation of medicinal plants, including issues related to biotrade, intellectual property rights and equitable sharing of benefits.
- Management of integration with conventional medicine
- Examples of best practice.

The above would lead to the provision of advice to Ministers, covering the following:

- A range of options for the development of national policy frameworks to include the provision of health services and conservation and sustainable use of medicinal plants, that could be developed into guidelines;

- Workforce and educational requirements; standards of practice, including regulation, accreditation systems and competencies,
- A framework by which to proceed, gathering and sharing information amongst Ministers (Bodeker, 1999).

SAFETY

The first concern expressed by most health authorities regarding traditional and complementary medicine is "Is it safe?" Clearly, national drug development strategies for herbal medicines must have safety as a basic premise. Research on herbal medicine in the past has tended to be pharmacological in nature. WHOs' Guidelines on the Evaluation of Herbal Medicines consider clinical evaluation to be ethical in contexts where drugs have been in traditional use for long periods of time.

A model for clinical evaluation of herbal medicines has been developed by Prof Ranjit Roy Chaudhury, W.H.O's South East Asia Regional Office:

1. Toxicity testing of the plant in two species of animal for acute and sub-acute toxicity
2. A modified, shorter toxicity testing if the plant has already been used in man or is in such use now
3. Administration of the total extract or combination of plants, if used, in exactly the same way as it is prepared and used by the population.

Roy Chaudhury has noted the differences between this approach and that of conventional drug evaluation methodology:

- efficacy testing is carried out on humans rather than on animals, o human studies are undertaken subsequent to modified, shortened toxicology studies have shown that the substance is not toxic in animals,
- the duration of the toxicity studies is reduced to six weeks for plants that are already in common use,
- the plant or mixture of plants is administered to subjects in the same manner in which it is used in traditional medicine (Roy Chaudhury, 1992).

The Ministry of Health of Malaysia is presently working to set up a national centre for herbal medicine which will have the repsonsibility of ensuring the safety of herbal medicines marketed in Malaysia. This central model of safety checking is in the process of being developed in Britain as well, where the National Poisons Unit and the Royal Botanical Gardens at Kew have

collaborated to set up a Chinese Traditional Medicine Screening Centre, where Chinese medicines, very popular in the UK, can be tested to establish:

a) that what the label says is in the packet is indeed in the packet
b) that there is nothing in the preparation that is not on the label
c) that there are no toxic materials in the preparation
d) that the concentrations reported to be present are indeed present.

While safety of traditional medicines must be of the highest priority, it is important to note that the Chinese Medicine screening Centre at Kew in Britain has found relatively few examples of serious toxicity and their overall verdict on these medicines is that they are safe for public use.

It is also important to note that the toxicities associated with herbal medicines are likely to be substantially less than those found with modern pharmaceutical drugs. For example, research conducted in the United States, 5 1% of FDA-approved drugs have serious adverse effects not detected prior to their approval. 1.5 million people are sufficiently injured by prescription drugs annually that they require hospitalization (Moore, 1998).

Once in hospital, the problem may be compounded. The incidence of serious and fatal adverse drug reactions (ADR's) in US hospitals is now ranked as between the fourth and the sixth leading cause of death in the United States, following next after heart disease, cancer, pulmonary disease and accidents (Lazarou, et al., 1998).

EVIDENCE AND RESEARCH: DESIGNING A NATIONAL AGENDA

The call for evidence on the effectiveness of traditional and complementary therapies has at its heart a demand for randomized controlled clinical trials (RCT's) on therapeutic modalities. However, there are many additional and important ways of gathering evidence other than the RCT alone. The RCT does not give information of effects of a treatment over time. Clinical observational studies are called for here. Population studies are needed to look at patterns of utilisation, expenditure, benefits and adverse effects.

Evidence of therapeutic effectiveness or mechanism of action are not needed to promote CM/THC utilisation or to achieve consumer satisfaction.. This is happening of its own accord.

Basic research into the physiologic links and molecular bases of therapeutic outcomes and mechanisms of action is needed in the longer term.. Where employed, basic research methodologies need to be generated to sensitively capture aspects of traditional medicine practice and theory that may appear intangible - e.g. energy, spiritual influences, etc.

The needs of interest groups in special situations - e.g. women, children, the poor, the elderly and those with special medical conditions - must be recognized and given priority in the development of national research agendas into THC.

Macroeconomic factors such as devaluation of currencies, including as a result of externally-imposed structural adjustment programmes, result in a 16% shift by from modern to traditional medicine, even in urban populations (AfDB, 1995). When women were the heads of households - a situation where poverty is greatest - the shift to traditional medicine was even higher (18%). Personal reports from medical colleagues in Tanzania suggest that the introduction of user fees has resulted in a substantial shift away from modern medicine towards traditional medicine. In interviews with traditional healers in the Kilimanjaro, I was told by several that they are experiencing substantially greater demand for their services at present (Lambhini Traditional Healers' Association, Tanzania, 1997. Personal communication). These trends highlight the need for cost-benefit research comparing the affordability and effectiveness of modern and traditional medicine and the affordability of each, particularly to vulnerable populations.

Prevention of disease is an area of fundamental importance in complementary health systems. Dietary and nutritional approaches to prevention provide opportunities for the study of prevention, as does the use of herbs and traditional forms of exercise (e.g. yoga) in promoting a balanced state of health. Accordingly, systematic research should be conducted into effective prevention practices

In all therapeutic settings, western and traditional, belief and attitude have an influence on treatment outcomes. A "placebo", or "meaning response," effect is an important component of many therapies. The extent to which therapeutic outcomes are based on expectancy is an important area of study.

WHO's Quality of Life Assessment includes spiritual dimensions in assessing an individual's quality of life. Here, "spiritual" relates to the sense of meaning regarding the self or extending beyond the self. The spiritual dimension of life and well being is central to many traditional and complementary health systems. Our own research indicates that 12% of those who use CM providers in Britain use the services of

'spiritual healers'. This trend, its origins and outcomes are important areas of research.

There is a need for comparative evaluation of both traditional and conventional medical methods for treating the same condition to identify safe and efficacious treatments that are locally available. This may also include the study of cross-cultural/cross-geographic healing practices to identify common treatments and/or to combine evidence for a specific herb or treatment regimen. Comparative studies could assess feasibility, cost-effectiveness, and environmental impact as well as specific biomedical outcomes.

Combination therapy should also be studied. For example, traditional and Western-based medicine are often used simultaneously in the treatment of certain chronic diseases in Asian medical systems, such as the Ayurvedic medical system of India and Traditional Chinese Medicine. Caution should be exercised to address cultural bias in the assumptions, methodologies and concepts employed in comparative research.

The levels at which a research agenda should promote research would include: the individual; the family and community; the wider population; the ecosystem/ environment.

The absence of evidence for many THC and CM modalities does not imply the converse - i.e. evidence of absence of effect. Rather, lack of research funding in this field reflects the lack of health policy interest in THC/CM. This has meant that scientists working in this area have been severely constrained in the evidence which they have been able to generate. The result has been that demand and THC/CM utilisation have outstripped the availability of useful information.

Substantial increases in funding are clearly necessary to support an expanded research endeavour. Funds should come from all levels of the health sector and from international agencies and from private medical charities.

PRIORITY DISEASES

Where modern medicine is expensive or less effective than desired, the public will often turn to traditional medicine in the management of serious disease. This is certainly the case with HIV/AIDS and malaria.

HIV/AIDS

As the AIDS crisis leads an increasing number of countries to question their priorities in health expenditures, there is an emerging awareness that traditional health practitioners (THP's) can play an important role in delivering an AIDS prevention message. There is growing recognition that some THP's may be able to offer treatment for opportunistic infections (OI's). At the same time, there are concerns about unsafe practices and a growth in claims of traditional cures for AIDS.

In Uganda, for example, where there is only one doctor for every 20,000 people, there is one traditional health practitioner per 200-400 people (Green, 1994). In such settings, partnerships may be the only way that effective healthcare coverage can be achieved in managing the twin epidemics of AIDS and malaria. Clearly, such partnerships not only make good public health sense but, based on a growing body of pharmacological evidence, may also yield important preventative and treatment modalities.

Information sharing and educational programmes in South Africa have resulted in THP's providing correct HIV/AIDS advice as well as demonstrations of condom use. One such programme trained 1510 THP's and it was calculated that during the first ten months of the programme, some 845,600 of their clients may have been reached with AIDS/STD prevention messages. In similar programmes in Mozambique, traditional healers learned that AIDS is transmitted by sexual contact, by blood and unsterile razor blades used in traditional practice. In a follow-up evaluation, 81% of those trained reported that they had promoted condom use with at least their STD patients (Green, 1997).

The Ugandan NGO, Traditional and Modern Health Practitioners Together Against AIDS (THETA), was established in 1992 to conduct research on potentially useful traditional medicines with HIV-related illness and to promote a mutually respectful collaboration between traditional & modern health workers in the fight against AIDS. THETA has conducted workshops to share knowledge on AIDS prevention and also treatment of OI's using local herbal remedies.

Traditional healers participating in clinical observational studies of their herbal medicines have subsequently sought 'training' in prevention, education, and counselling issues as well as in basic clinical diagnostic skills. A 1998 UNAIDS sponsored evaluation of THETA found that it had reached 125 THP's (44 women and 81 men) in 5 districts of Uganda. 50,000 people were found to have benefited from the improved services offered by traditional health practitioners over a period of 2 years (Kabatesi, 1998).

THETA has worked with traditional healers' in evaluating several traditional treatments used locally for OI's. The research has found traditional medicine to be "better suited to the treatment of some AIDS symptoms such as herpes zoster (HZ), chronic diarrhoea, shingles and weight loss. THETA has conducted controlled clinical trials on a Ugandan herbal treatment for herpes zoster. Comparing subjects with herbal treatments with controls using acyclovir, the conventional treatment for HZ, both groups were found to experience similar rates of resolution of HZ attacks. The traditional medicine group had less super-infection and showed less keloid formation than did subjects on acyclovir. HZ pain resolved significantly faster in the herbal group. The investigators concluded that herbal treatment is an important local and affordable alternative in managing HZ in HIV infected patients in Uganda (Homsy et al., 1999).

A new Task Force established in Kampala in early 2000, includes a research initiative, in which the Commonwealth Working Group on Traditional and Complementary Health Systems, with its partner organisation the Global Initiative For Traditional Systems (GIFTS) of Health, is playing a co-ordinational role. The research initiative consists of a network of researchers and institutions to build a research programme which will identify, assess, and develop safe and effective local treatments for HIV-related illnesses. The programme will use simplified but controlled clinical protocols to conduct rapid evaluations of promising treatments. It will build databases for information sharing on the successes and failures of local treatments. It will be grounded in an intellectual property rights framework to protect the rights of local knowledge holders, learning lessons from a few existing programmes in Africa. Recognizing the global, unsustainable pressure on wild stocks of medicinal plants, sustainable horticulture will be promoted for priority species. This strategy will be designed to guide promising herbal treatments through to the stages of production and development of safe, effective and affordable medicines. It will emphasize, where applicable, the local production and dissemination of useful herbs at the national, community and family level, towards an African solution for combating AIDS in Africa (Bodeker et al., 2000).

MALARIA

Currently, modern pharmaceuticals are not available in constant supply in areas most affected by malaria - particularly in sub-Saharan Africa and in South and SE Asia. With increasing drug resistance and the high cost of drugs, the use of herbal antimalarials in these regions is popular. Despite growing policy interest in traditional medicine, and the seminal 1997 Dakar meetings on malaria recommending research into herbal antimalarials, there has been almost no research into the clinical effectiveness of herbal remedies as they are used in real life.

The two most effective drugs for malaria originate from plants: quinine from bark of the Peruvian *cinchona* tree, and artemisinin from the Chinese antipyretic *Artemisia annua* L. Other plants are likely to contain as yet undiscovered antimalarial substances. While much research has focussed on trying to isolate and purify these from plants, there is concern that conventional isolation and extraction methods may miss synergistic mechanisms of action found in traditional antimalarials.

In December 1999 the Research Initiative on Traditional Antimalarial Methods (RITAM) was established designed to develop a strategy for more effective, evidence-based use of traditional medicines that can also inform malaria control policy decisions <http://mim.nih.gov/partnerships/index.html>.

RITAM has developed four specialist groups to implement a research strategy designed to make a significant contribution to malaria control programmes (Bodeker and Willcox, 2000):

1. Policy, advocacy and funding
2. Pre-clinical studies
3. Clinical development
4. Repellance and Vector Control.

The first clinical trail by RITAM will begin in Madagascar in October 2000 to evaluate a Malagasy plant that appears to have the effect of reversing resistance to chloroquine. Other clinical studies are being developed in East and West Africa, in India and in Vietnam, including research designed to evaluate the prophylactic effects of selected medicinal plants.

MEDICAL EDUCATION & TRAINING IN CM/THC

In light of the growing demand for complementary medicine (CM) by the public, 60% of American medical schools now offer courses in CM, In the UK, the General Medical Council recommends that British Medical Schools offer introductory courses in CM in order to prepare future doctors to respond to the fact that half or more of their patients will be using CM.

It is estimated that 40% of British medical schools now offer introductory courses in CM. At Oxford University, the Medical School offers courses in CM for first and final year medical students, based on an evidence-based approach to evaluating complementary therapies.

With the licensure of osteopaths and chiropractors as registered professions in the UK and in the US, and with acupuncture being on track for professional registration, a new range of complementary health professions is emerging. This is creating new developments in health professional education and the development of related educational institutions.

The same development in medical education is needed in non-industrialised countries, where an even greater majority of patients seen by medical doctors are also using traditional medicine. In Vietnam, all medical students are required to undertake sixteen courses in traditional medicine, including herbal medicine, acupuncture and therapeutic massage.

Courses in TH/CM should be available in undergraduate health science programmes. They should also be a required part of Continuing Professional Education. There is a need for public education on the nature and scope of a health system which incorporates TH/CM practitioners. TH/CM practitioners should be involved in curriculum design and instruction for all courses.

It is widely recognised that there has been a progressive erosion of indigenous knowledge which informs traditional health care systems. This has weakened the quality of traditional healthcare services. Substantial increases in government, Commonwealth and international allocations to the traditional health sector are urgently called for to support preservation of traditional health knowledge systems and their applications.

Trends world-wide suggest that the new century will see the emergence of an integrated approach to health care, driven in large part by consumer demand. This integrated approach is likely to be professionalised, thus responding to public demand for a range of therapeutic options that are safe effective and affordable.

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A PAPER ON

PROCESS TECHNOLOGY FOR THE EXTRACTION OF MEDICINAL /AROMATIC PLANTS ON A PILOT SCALE

BY

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TO BE PRESENTED AT THE

WORKSHOP ON STRATEGIES TO STRENGTHEN THE UTILIZATION OF MEDICINAL AND AROMATIC PLANTS IN THE NATIONAL HEALTH CARE SYSTEM.

11-13TH JULY, 2000.

ABUJA.

ABSTRACT:

Studies carried out on the multipurpose pilot plant used for the extraction of both medicinal and aromatic plants have been a source of technological into-data bank meant for prospective scale up to the industrial level.

Vital process data such as solvent requirement (e.g purity, type, volume etc), steam requirement (wet or dry, pressure, temperature, rate etc) possible size requirement (fine, coarse, etc), storage of product (tin, aluminum containers, glass containers etc), process time, raw materials requirement (dry, wet, period of collection etc) and process optimization (essential because of financial implications) have been worked out and these will form the basis on which the scale-up calculations are made. Essential oils were extracted from the following plants:-

Eucalyptus citriodora, Eucalyptus camaldulensis, cymbopogon citratus (lemon grass), Zingiber officinale (Ginger) and Lippia multiflora. Their yields were encouraging and comparable to literature save for ginger. Similarly extracts gotten from medicinal plants are being formulated into drugs for the management of sickle cell anaemia (NIPRISAN), Skin fungi attack (AF1) and AIDS (NIPRD-HIV). These E. Oils and medicinal plant extracts are still undergoing laboratory microbial activity test and quality control test.

INTRODUCTION

Medicinal plants are plants that contains drugs constituents and are used as a major source of drugs for the treatment of various ailments all over the world. International bodies like WHO, UNDP, UNIDO etc, are pursuing and emphasizing vigorously on the use of medicinal plants in developing countries through the promotion of traditional system of medicine especially in countries like India, Nepal, Nigeria etc.

The Developed Countries to depend, to a large extent on medicinal plant resources in their health care system. In the US for instance, consumers have paid up to $3billion (1959-74) for drugs derived from plants which is about 25% of all new and refilled prescripts dispensed from community pharmacists. Similarly in USSR 30% of the drugs prescribed each year are of vegetable origin.

Researchers have now reverted back to the use of medicinal plants for biologically active compounds. For instance here in NIPRD, medicinal plants have been exploited fully especially in the management of sickle cell anaemia, skin fungi attack and of recent the much talked about HIV. One cannot talk alone on medicinal plant without talking about aromatic plants, as widely known aromatic plants produce essential oils.

NIPRD's pilot plant have been able to extract oils from the following plants: Eucalyptus citriodora, Eucalyptus camaldulensis, cymbopogon citratus (lemon grass), zingiber officinale (Ginger) and Lippia muitiflora. Medicinal Plant extracts too have been extracted for the management of HIV, skin fungi attack and sickle cell anaemia. The main focus of this paper is to therefore enumerate in details the process technology development for the extraction of medicinal as well as aromatic plant on a pilot scale.

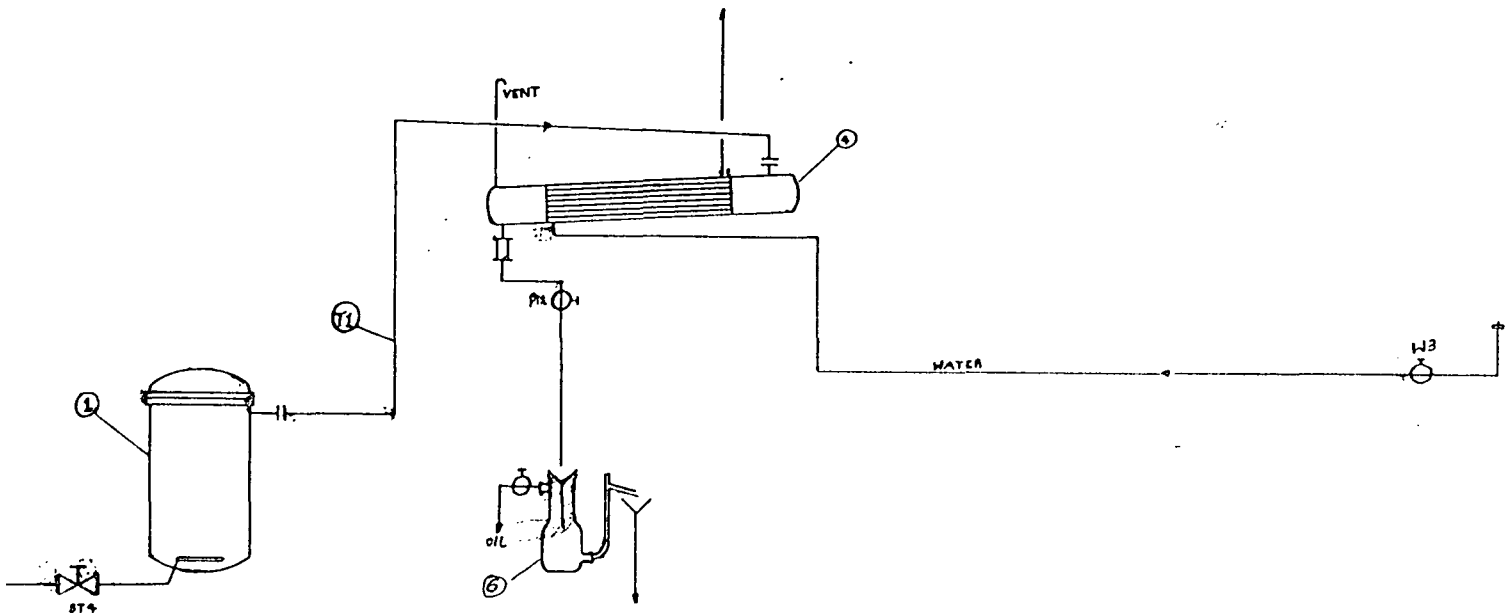
Process Procedures

1. Steam distillation for essential oil extraction

- Once the plant materials are made available, the boiler should be fired to generate steam
- Simultaneously branchlets or grasses as the case may be are weighed and charged into the extract (500L) carefully and well arranged. The extractor can take as much as 150kg depending on the density of the material.
- Place a perforated grid over the well packed bed (to avoid channeling) and close the top lid tightly.
- Ensure all valves are closed and check the availability of water then open condenser water inlet valve and observe the outlet water flow.
- Open steam valves (ST4), normally 2-2.2bar. Its flowrate could be measured by the vol. of water from florentine flask. It can be adjusted.
- Collect oil from florentine flask at interval of 30 minutes
- Shut steam valve (ST4) at the end of extraction (say 3hrs)
- Shut water valve (W3) say after 5-10 minutes
- Measure the volume of oil collected and calculate the percentage yield
- Drain off the steam condensate from the still bottom. Discharge the spent material via the pulley block

2. Medicinal plant extractions

- Plant material to be crushed in the case of bark, roots, stem etc to smaller particles. For branchlets sometimes leaves could be picked.
- Weigh and charge the plant materials into the extractor properly.
- Pump in known volume of solvent using the circulating pump into the extractor.
- The solvent is circulated for say 2-3 hours.
- The extract is then pumped into the Reboiler (8) via a filter (12)
- It is heated up with steam, the solvent evaporates through the column (9) into the overhead condenser (10), it is condensed and then passes through coil type cooler and collected in the solvent tank (11) or receivers (2).
- Solvent recovery is done until the extract is free from it and the concentrated extract is drained from the reboiler.
- Further concentration of extract can be done on the rising and falling film evaporator.



ITEM	LEGEND
PI2.	VALVE
6	SEPARATOR
ST4	STEAM VALVE
4	CONDENSER
W3	WATER VALVE
T1	THERMOMETER
1	EXTRACTOR

STEAM DISTILLATION

N·I·P·R·D — ABUJA

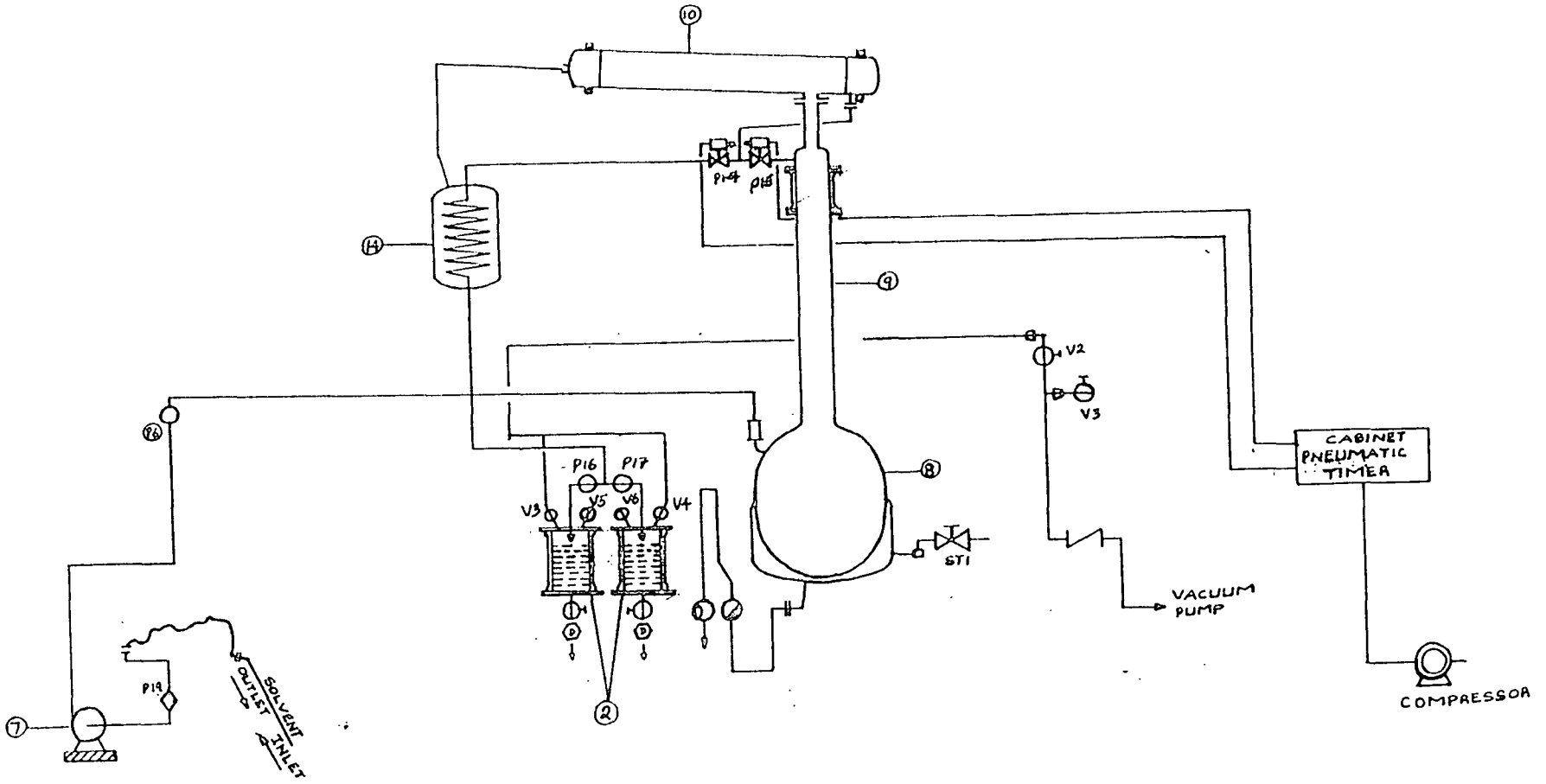
UNIDO PILOT PLANT DAG 01

CONCEPT: NARASIMHA B. MARLA UNIDO

PROJ. MANAGER: PROF. T. DE SILVA UNIDO

NATL. PROJ. DIRECTOR: PROF. C.O.N. WAMBEBE

DRAWN: ELIAS N. AMLABU



FRACTIONAL DISTILLATION

ITEM	LEGEND
2	VAT
P19	VALVE
P17	VALVE
P16	VALVE
P15	VALVE
P14	VALVE
10	CONDENBER
9	COLUMN
8	REBOILER
7	CIRCULATING PUMP
P6	VALVE
V4,V5,V6	VALVE
V2,V3	VALVE
ST1	VALVE

N.I.P.R.D — ABUJA	
UNIDO PILOT PLANT DRG	
CONCEPT	NARASIMHA B. MARL
PROJ. MANAGER	PROF. T. DE SILVA
NATL. PROJ. DIRECTOR	PROF. C.O.N. WAMBEBI
	ELIAS N. AMI ABII

Results

i Extensive work was carried on the following oils:-

Plant material	Average yield(%)	Literature value(%)
E. Camaldulensis	0.96	?
E. Citriodora	2.06	1-2
Zing. Offi. (Ginger)	0.61	1-2.7
Lippia multiflora	0.68	0.5
Cymbopogon (lemon grass)	0.48	0.3-0.8

II Comparison: Pilot scale Vs bench scale

Plant material	Pilot scale	Bench scale
E. Citriodora	2.057	6.83
Zingiber officinale (ginger)	0.61	0.46
Cymbopogon citrates (lemon grass)	0.48	2.39

III Medicinal plant extractions

	%Yield
NIRPISAN	9 -14
AF1	7
HIV	10.6

Conclusions

1. Information from studies carried on the pilot scale extractions form the basis for correct calculations to be made for enlargement (industrial level).
2. Both medicinal/aromatic plant extracts have proved to be useful to mankind (health care)
3. The gains to be derived from the process on an industrial level are enormous especially as it serves as a data bank for investors.
4. It is a cleaner, non contaminating way of extracting plant materials especially when compared to the methods used by local herbalist.
5. Solvents other than water, have been found to be efficient in plant extraction.

BIO-GUIDED EXTRACTION / ISOLATION OF A MEDICINAL PLANT

BY

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ABSTRACT

Plants are sources of drugs. The selection of a plant specie for scientific investigation is the most crucial factor.

There are different ways in choosing a plant.This can be through random collection,literature or the exploitation of ethnomedical information . The latter, represents a promising approach in order to obtain plant material with documented pharmacological properties.

The process that leads from the plant to a pharmacologically active, pure constituent is long, involves a series of consecutive steps and is expensive. The first step in this direction is the screening of the crude extracts of the medicinal plants in a bio-guided approach.

INTRODUCTION

Man depends on plants for food, shelter, clothing, herbs, spices, soaps, toiletries, perfumes and medicine.

Before the 20th century, most drugs were obtained directly from plants. Today, about 80% of the world's population, rely on herbal medicines as a basis for their health care. A larger proportion of this group, are from the developing countries.

In the traditional form of medicine, these plants are used in the crude form where they are collected from the wild. In the traditional medicine, a plant is often used for the treatment of various diseases. For example, *Afraegle paniculata*, the water extact of the root is used to facilitate delivery, to treat rheumatic crises, as an anticonvulsant and as an analgesic [Napralert]. The multiuse of the plant suggests that it contains various biologically active chemical constituents. The same plant is found to contain different types of coumarin and quinoline alkaloids.In cases like this, it would be necessary to link activity to a constituent. This process, is referred to as bio-guided isolation.

The isolation of active constituent, has some advantages.It helps in the conservation of plant materials. This is because,

medicinal and aromatic plants used in traditional medicine are usually collected from the wild. Excessive harvesting, would lead to genetic erosion and the exploitation of natural habitat, such could lead to the extinction of some valuable plant species. The isolation of the constituent responsible for each activity, would help in a large production of the constituent. In so doing, the chances of the plant going into extinction from massive collection from the wild is reduced. Isolation ,would help to determine structure-activity relationships with the active compound serving as a 'lead' for a more desirable molecule having greater efficacy or fewer or less severe side effects.

Scientific investigation of these plants is expensive especially when laboratory animals are used at the screening stage. The development of relatively, inexpensive bioassay technology has increased the interest to screen for drugs from plants.

The ultimate goal in plant reserch is the use of bioassay models, to identify and develop substances with a desired biological activity.

BIOASSAY METHODS

Plant crude extract, is a mixture of various chemical constituents eg flavonoid, steroid, alkaloid etc. Each constituent may be responsible for a specific activity.

Isolation of the active constituent is achieved by a bio-guided approach with a model, which should be simple, rapid, reproducible, inexpensive and can accomodate the screening of a large number of compounds.

Bioassays, can be carried out on lower animals [microorganisms, insects, molluscs], isolated subcellular systems [enzymes, receptors or organelles], cultured cells of human or animal origin, isolated organs of vertebrates or whole animals.

The following are few examples of established bioassays;

[A] Brine shrimps lethality,

This is used to study the cytotoxicity of a plant extract. A cytotoxic drug, is considered to be pharmacological active. The test is carried out on *nauplii* of *Artemia salina* [brine shrimps]. The eggs of *Artemia salina* is cheap and easily available. It can be purchased in a pet shop. The eggs hatch into a *nauplii* after 48 hrs in seawater.

The experiment is carried out as described by G. Persoone [1980]; Meyer et al [1982]. *Artemia salina* eggs are placed in a vessel containing seawater. After 48 hrs of incubation at room temperature, the eggs hatch and mature into a *nauplii*. The *nauplii* is harvested and stored in small beaker, containing sea

water.

Plant extracts are prepared in triplicates at 1000 and 10 µg/ml [or less for more potent plant material] in vials/microwells. Extracts are prepared in water. Water insoluble extracts can be dissolved in DMSO or Tween 80 . About 10 - 15 shrimp is added into each vial/microwell containing the plant extract. After, 24 hrs, the number of deaths over the number of live shrimp is recorded. The result, is analysed statistically with the Finney Computer Programme.

[2] Crown gall tumours on potato disc

Crown gall tumours is produced by the Gram negative bacterium, *Agrobacterium tumefacins*. It affects plants. The inhibition of crown gall tumors on discs of potato tubers is an indication of antitumor activity. The procedure used, is as described by Galsley et al, 1980 and McLauglilin et al ,1988.

Agrobacterium tumefacins with a Ti [Tumor-inducing], is used for the experiment. About 20 ml of sterilized, cooled nutrient agar is poured on a petri dish. Bleached red-skinned potatoes is bored with a 1.8 cm cork borer into a cylindrical shape. The potatoe cylinders is sliced into a disc shape and placed on the set agar. A petri dish, can take about 5 discs. On each disc, add about 0.5 ml of an innoculum [1.5 ml water,2.0 ml bacteria

and 0.5 ml sample (4 mg of sample in 1 ml DMSO)] For control, the sample, is replaced with 0.5 ml of DMSO. The experiment is carried out in triplicates. Each petridish, is covered with a parafilm and aluminium foil and stored in the dark at 27°C. After 12 to 21 days the percentage of inhibition of crown gall tumors per disc is calculated.

$$\% \text{ Inhibition} = \frac{\text{Average tumors per disc of sample} \times 100}{\text{Average tumors per disc of control}}$$

LARVICIDAL TEST

This is a cytotoxicity or lethality test. It is similar to the brine shrimp lethality test except here, the larvae stage of anopheles mosquito is used for the experiment.

The extract is tested at the concentrations of 1000 µg/ml, 100µg/ml, 10 µg/ml and 1 µg/ml. 100 ml of anopheles mosquito, is added to each test solution in a beaker. After 24 hr. exposure at room temperature, the number of deaths over live larva is recored. The result is analysed statistically.

NEMATICIDAL ACTIVITY

To study the nematicidal properties of a plant extract, the larvae of Meloidogyne incognita is used with lettuce seedlings as the host plant. The method used for the experiment, is as described by Jandl et al 1994.

The experiment is carried out in a 6 cm petri dishes. Sephadex G-150 is used as a matrix. The size of the sephadex is such that allows the larvae to move easily and be able to locate the host plant. About 1/4 of the petri dish is demarcated with a barrier. 50 mg of sephadex, is mixed with a known concentration of the test solution and introduced at the 1/4 section . Nematodes are inserted. On the 3rd day, 140 mg of sephadex is mixed with water and introduced at the 3/4 section. The barrier is removed, and lettuce seedlings inserted. On the 4th day nematodes are counted. The same experiment is prepared as controls without the plant extract.

The result is presented as a percentge of the decrease in number of nematodes at the roots compared to controls.

$$\% = \frac{\text{control - test x 100}}{\text{control.}}$$

ANTIFEEDANT ACTIVITY

The experiment is carried out with the leaves of the bean plant, Phaseolus vulgaris var. Saxa and the fourth instar larvae of the Mexican bean beetle *Epilachna varivestis* [Muls.].

The procedure used is as described by Kraus et al, [1984]. The experiment is carried out on a petri dish. The dish is lined with a moist filter paper. A piece of gauze, is placed on the paper. The test leaf [left half treated, right half untreated] is placed on the gauze. Two instar larvae are introduced. The petri dish, is covered . After 24 hrs, the consumed area of the leaf is determined. The activity, is indicated by the rate of feeding.

$$\text{Activity} = \frac{\%\ \text{consumed untreated area}}{\%\ \text{consumed treated area.}} \times 100$$

ANTHELMINTIC ACTIVITY

A number of in vitro anthelmintic test systems exist. For example *Caenorhabditis elegans* is used in vitro for the screening of potential anthelmintics. C.elegans, has a resonable degree of selectivity. The model is cheap and can be easy to operate. About 200 or more tests can be carried out a day with this model.The method used is as described by Simpkin and Coles[1981]

The method, involves the use of free-living soil nematode C.elegans. 10 ml of a worm suspension, is drawn with a micropipette into two ml wells of polystyrene plates, containing a known concentration of the plant extract. A control containing

no drug, is also prepared. After seven days of incubation, the untreated wells are compared to the controls and assessed for increase in the number of the worms and their motilities. Extracts are scored as very active [+++], active [++] or not active [+].

ANTIMICROBIAL ASSAY

Bactericidal

Bioauthography system is used for the isolation of active constituent responsible for the antimicrobial property from a plant extract. The method is as described by Homans et al, [1970] involves the separation of a plant extract on thin layer chromatograms. The developed chromatogram, is sprayed with a suspension of *Bacillus subtilis* or *Pseudomonas flurescens*. This is incubated in a humid atmosphere to the growth for the bacteria. After a 24 hr incubation, the inhibition zones are visualized by a dehydrogenase-activity-detecting tetrazolium salt. The tetrazolium salt, is converted into the corresponding intensely colored formazan by metabolically active bacteria. Antibacterial compounds, appear as clear spots against acoloured background.

Fungicidal

The bioauthography, is also, suited for the detection of fungicidal compounds in a plant extract. Unlike the bactericidal activity, the thin layer chromatogram, is sprayed with a suspension of a fresh solution of *Cladosporium cucumerinium*. The plate is incubated in a dark and humid enviroment. Clearly visible zone on a dark background, indicate the presence of fungitoxic compounds.

BIOGUIDED ISOLATION

Isolation of the antibacterial agent from *Berlina grandiflora* [BG] using the Bioauthograpthic technique [Enwerem et al, 1999].

BG is a plant that is used in the traditional form of medicine as an antibacterial agent. The dried stem bark of BG, was successively extracted with hexane, ethylacetate and methanol. The plates were developed with a solvent system that gave sufficient separation of the compounds. The different plates were subjected to antibacterial assay following the method as described by Homans et al, [1970]. The ethylacetate extract, was found to contain the active fraction. This extract was subjected to column chromatography. Similar fractions were combined.Seventeen fractions [I - XVII]were obtained . These were assayed for activity.Fraction XII, was the active fraction .

Diethlyether was added to fraction XII. Two fractions were obtained, Diethylether soluble [XIIa] and insoluble [XIIb]. On bioassay, XIIb was found to be the active fraction. The active fraction, was subjected column chromatography wiith silica gel as the adsorbent. Elution, was carried out with chloroform,methanol in the order of polarity. Similar fractions were combined and assayed. Fraction XIIb6 eluted with chloroform/ methanol mixture [95:5]was found to be the most active.Further purification of XIIb6 through recrystallization in ethanol, lead to the isolation of Apigenin as the active constituent. The structure was confirmed from m.p, NMR[proton and 13 carbon], and MS.

Bioassay-guided isolation of a diastereoisomer kolavenol from *Entada abyssinica* active on Trypanosoma brucei rhodesiense by Freiburghaus et al[1998].

Entada abyssinica is a plant used by traditional healers in Uganda for the treatment of sleeping sickness. The in vitro model used by the scientists, was as described by Obexer et al [1995].

The dried and powdered root bark was extracted with petroleum ether followed by extraction with dichloromethane. The dichloromethane extract, was chromatographed on a neutral alumina column and eluted with mixtures of ligroin - t-butyl methyl ether [t-BME]-ethylacetate[ETOAC] of increasing polarity, to give eight fractions [1 - VIII]. The trypanocidal activity of these fractions were tested. Fraction VI, was active. VI, was further separated on a flash column with neutral column, as the adsorbent material. Elution, was carried out with a mixtures of hexane - ETOAc. Four fractions were obtained. Only fractionVI.3 showed trypanocidaly activity. Fraction VI.3 was further chromatographed on silica gel column and eluted with mixtures of ligroin - t-butyl methyl ether [t-BME]-ethylacetate[ETOAC], to give three fractions. The fraction VI.3.2 exhibited trypanocidal

activity. VI3.2, was further chromatographed on silica gel column and eluted with toluene-acetonitrile to give two fractions. The two fractions, were equally active. However, only VI.3.2.1, was sufficient for further bioassay tests. Diastereoisomer of kolavenol, was isolated from VI.3.2.1 by HPLC on a preparative column. The eluting solvent, was a mixture of acetonitril - water .

CONCLUSION.

NIPRD has six technical departments with experienced scientists, in the area of pharmacognosy, pharmacology, phytochemistry,medicine, microbiology, pharmaceutical technology and virology.

Research is carried out in a collaborative manner by a team made up of different disciplines. Selection of medicinal plant, is based on ethnomedical survey. In addition to specific tests, the plant is subjected to a battery of tests for other activities. Through collaborative research work, extracts are prepared, sent to the appropriate department for bioassay. Feed back of information helps in bioassay guided isolation of active constituent.

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STRATEGIES TO STRENGTHEN THE UTILIZATION OF MEDICINAL AND AROMATIC PLANTS IN THE NATIONAL HEALTH CARE SYSTEM

COMMERCIAL PRODUCTION OF HERBAL MEDICINES

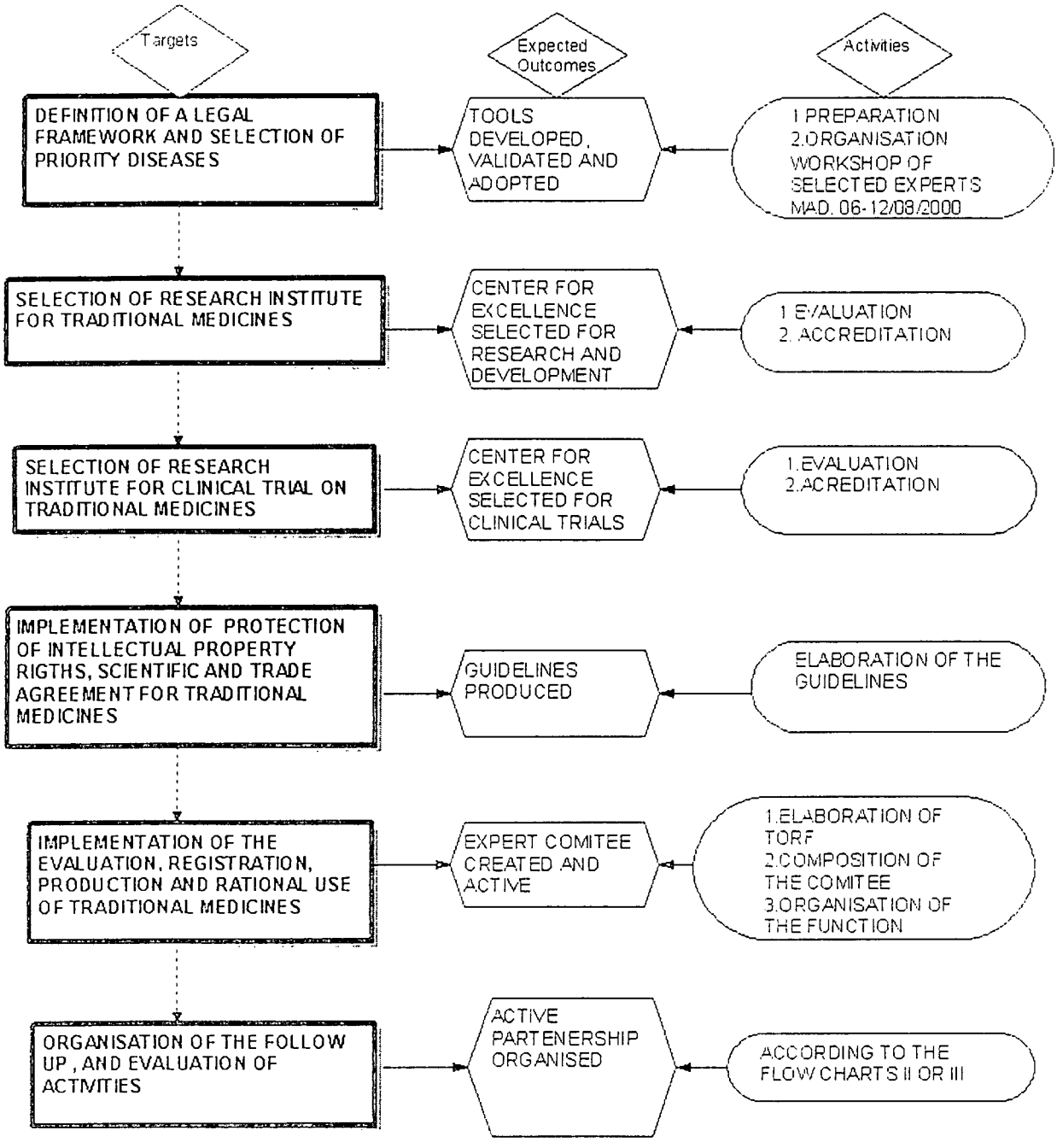
ICS UNIDO NIPRD

Abuja 11-13 july 2000

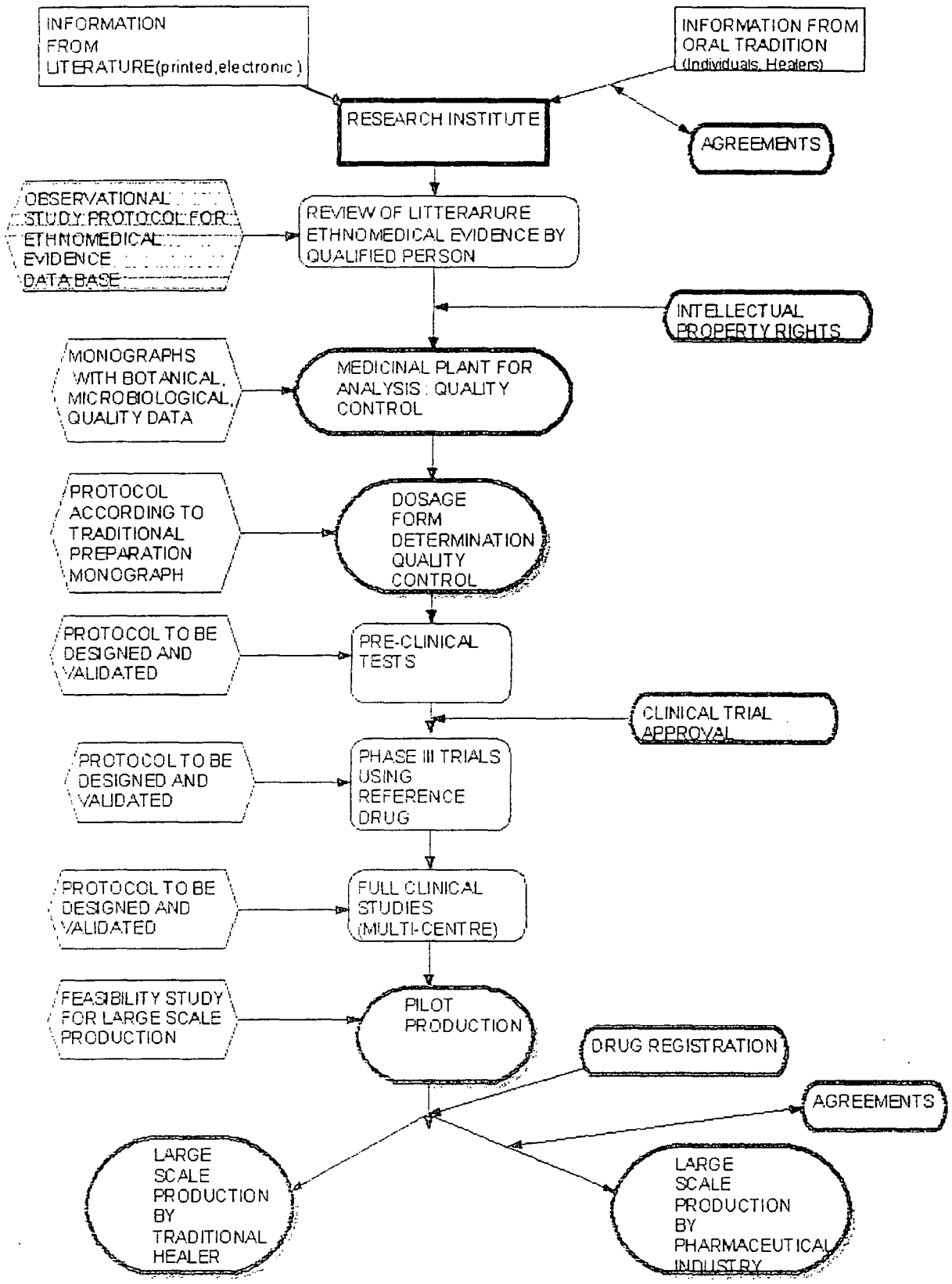
Dr Mariane NGOULLA

WHO/AFRO Technical Officer TRM

FLOW CHART I


Targets
Expected Outcomes
Activities
DEFINITION OF A LEGAL FRAMEWORK AND SELECTION OF PRIORITY DISEASES
TOOLS DEVELOPED, VALIDATED AND ADOPTED
1.PREPARATION 2.ORGANISATION WORKSHOP OF SELECTED EXPERTS MAD. 06-12/08/2000
SELECTION OF RESEARCH INSTITUTE FOR TRADITIONAL MEDICINES
CENTER FOR EXCELLENCE SELECTED FOR RESEARCH AND DEVELOPMENT
1.EVALUATION 2. ACCREDITATION
SELECTION OF RESEARCH INSTITUTE FOR CLINICAL TRIAL ON TRADITIONAL MEDICINES
CENTER FOR EXCELLENCE SELECTED FOR CLINICAL TRIALS
1.EVALUATION 2.ACREDITATION
IMPLEMENTATION OF PROTECTION OF INTELLECTUAL PROPERTY RIGTHS, SCIENTIFIC AND TRADE AGREEMENT FOR TRADITIONAL MEDICINES
GUIDELINES PRODUCED
ELABORATION OF THE GUIDELINES
IMPLEMENTATION OF THE EVALUATION, REGISTRATION, PRODUCTION AND RATIONAL USE OF TRADITIONAL MEDICINES
EXPERT COMITEE CREATED AND ACTIVE
1.ELABORATION OF TORF 2.COMPOSITION OF THE COMITEE 3.ORGANISATION OF THE FUNCTION
ORGANISATION OF THE FOLLOW UP, AND EVALUATION OF ACTIVITIES
ACTIVE PARTENERSHIP ORGANISED
ACCORDING TO THE FLOW CHARTS II OR III

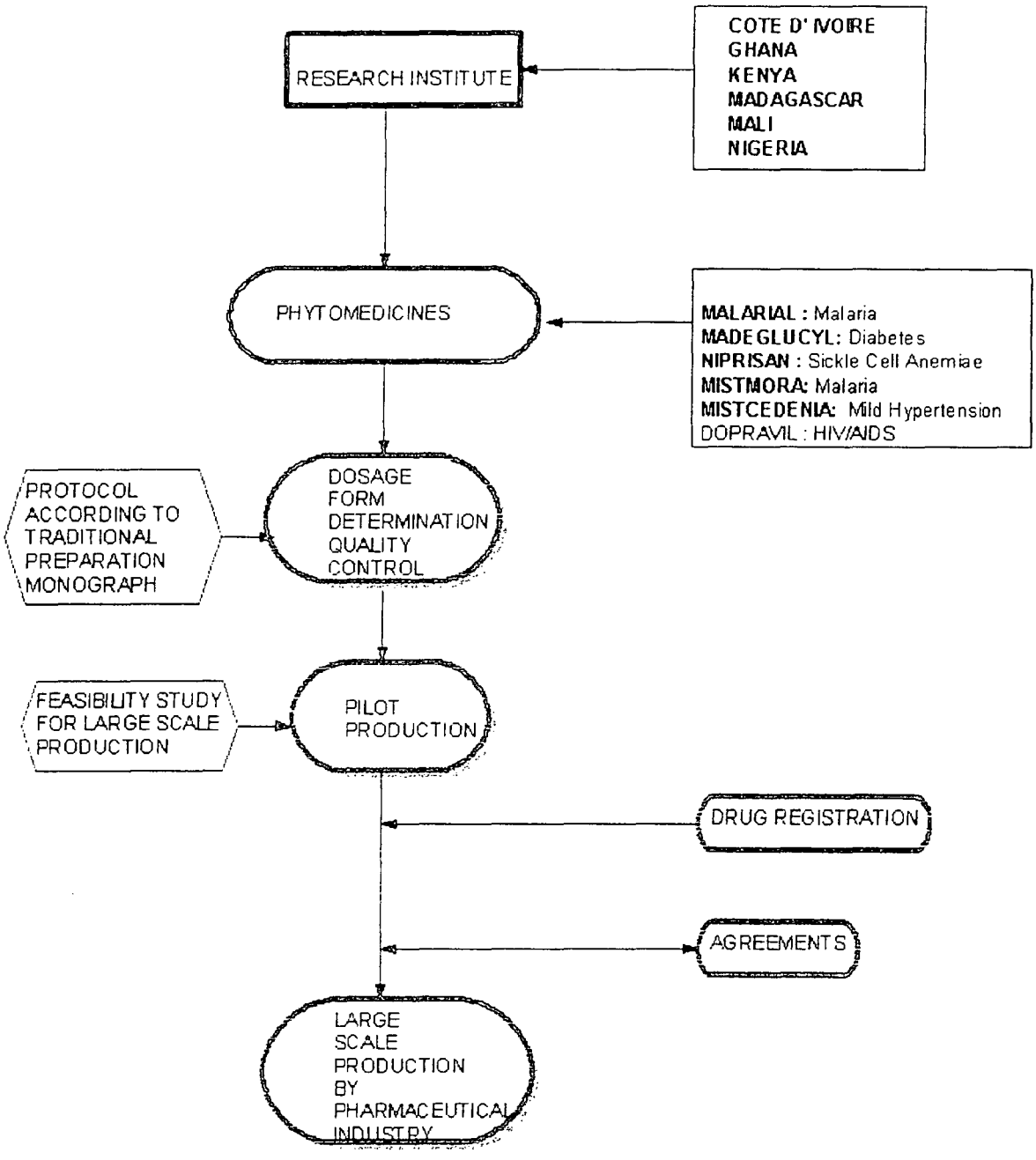
Flow Chart II



DRAFT FOR EVALUATION OF QUALITY, SAFETY, EFFICACY AND PRODUCTION OF TRADITIONAL MEDICINES WHO/AFRO

MN

FLOW CHART III



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CLINICAL TRIALS OF HERBAL MEDICINES: CHALLENGES AND PROSPECTS

BY

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1. PREAMBLE

In various cultures, at all times during the history of man, plants among others have been used extensively for the management of all kinds of diseases and ailments. It is apparent, looking back over thousands of years, that nature has provided the resources for treating prevailing ailments for various cultures globally.

In fact, it is generally believed that chronic ailments like diabetes, cancer, hypertension, etc which have defied modern curative therapied may respond to appropriate herbal medicines which are safely locked up in specified medicinal plants waiting to be identified.

The rich cultural heritages of the various cultures in the Third World Countries rely essentially on Traditional Medicine to meet their daily primary health care needs. In China, India, Thailand, Indonesia and Malaysia, the traditional methods of healing have been incorporated into their various national health care systems. In China, for example, the Chinese Traditional Medicine is fully incorporated into the national health care system while in India, Ayurvedic Medicine is recognised and practised along side Orthodox Medicine in the national health care system. In Africa, Traditional Medicine is not yet practised as a recognised and respected health care system. One of the reasons which has resulted into this state of affair is the apparent lack of quality clinical data using standardised herbal medicines to establish efficacy and safety. Standardisation of the raw materials, the processes and products of traditional medicine has also been mentioned often as a major obstacle to the introduction of Traditional Medicine into the national health care system in Africa.

WHO described clinical trials as follows:

A systematic study on pharmaceutical products in human subjects (including patients and other volunteers) in order to discover or verify the effects of and/or identify any adverse reaction to investigational products, and/or to study the absorption, distribution, metablolism and excretion of the products with the object of ascertaining their efficacy and safety. Clinical trials are generally classified into Phases 1 to IV.

WHO has further defined the purposes to be achieved in each phase of clinical trials as indicated below:

Phase I

This is the first trial of a new active ingredient or new formulations in man, often carried out in healthy volunteers. The purpose is to establish a preliminary evaluation of safety, and a first outline of the pharmacokinetic and, where possible, a pharmacodynamic profile of the active ingredient in humans.

Phase II

These trials are performed in a limited number (about 100) of subjects and are often, at a later stage, of a comparative (e.g. placebo-controlled) design. Their purpose is to demonstrate therapeutic activity and to assess short-term safety of the active ingredient in patients suffering from a disease or condition for which the active ingredient is intended. This phase also aims at the determination of appropriate dose ranges or regimens and (if possible) clarification of dose-response relationships in

order to provide an optimal background for the design of extensive therapeutic trials (i.e Phase III).

Phase III

Trials in larger (and possibly varied) patients with the purpose of determining the short-and long-term safety-efficacy balance of formulation(s) of the active ingredient, and of assessing its overall and relative therapeutic value. The pattern and profile of any frequent adverse reactions must be investigated and special features of the product must be explored (e.g. clinically-relevant drug interactions, factors leading to differences in effect such as age). These trials should preferably be of a randomised double-blind design, but other designs may be acceptable, e.g. long-term safety studies. Generally, the conditions under which these trials are carried out should be as close as possible to normal conditions of use.

Phase IV

Studies performed after marketing of the pharmaceutical product. Trials in phase IV are carried out on the basis of the product characteristics on which the marketing authorisation was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies. Although methods may differ, these studies should use the same scientific and ethical standards which are applied in premarketing studies. After a product has been placed on the market, clinical trials designed to explore new indications, new methods of administration or new combinations, etc. are normally considered as trials for new pharmaceutical products.

This paper will briefly consider the challenges and prospects regarding the clinical trials of herbal medicine.

2. CHALLENGES

It has been argued that since herbal medicine has long history of usage in some cases spanning over a thousand years with oral or written evidence of efficacy and safety, it is a wasteful process to conduct controlled clinical trials.

In Africa generally, the experties required for the preparation of specialised clinical trial protocols may not easily be available. Clinical trial management may pose another difficulty: Both the health facilities and personnel are already generally over burdened with emergencies which leave them with no resources and time to participate in the conduct of a good clinical trial programme. The substantial funds required for conducting a good clinical trial are usually lacking. The uncertainty regarding the precise chemical composition of herbal preparations may constitute a problem to some regulatory authorities regarding kinetics monitoring and management of severe unexpected adverse reactions. The possible undesirable interactions between herbal medicines and orthodox medicines is an area that may pose a serious problem since most patients may, on their own, take both orthodox and herbal medicines concurrently, even when advised against such a practice. The discipline required to keep proper records of all proceedings regarding Good Clinical Practice may be adversely affected by numerous pressures and diversions resulting from infrastructural problems and the socio-cultural settings. The hospital where such studies are to be carried out should ideally have a standard ethical

committee to review the protocols before the trial commences as well as monitor the conduct of the study. The qualitative and quantitative variations associated with plant constituents due to seasonal changes create an important problem vis-à-vis standardi (GLP) is not yet imbibed by most scientists in Africa. The reagents required to monitor the safety of such preparations including liver function test and kidney function test and other specialised diagnostic tests are usually imported from Europe and may be deteriorated before use due to lack of constant electricity supply. In fact, the psychological block against conducting a good clinical trial using herbal medicines may scare away some people from attempting to do such studies.

These real problems can be regarded as challenges which can be overcome if we are serious and determined. If we really want herbal medicines to be included in our national health care system we have no alternative than to conduct controlled clinical trials with these products. It is only then that we can be able to ensure that such herbal products that satisfy the regulatory authorities are consequently included in our national lists of essential drugs. Such a process will lead to the possibility of exporting the herbal products to other African countries and beyond.

In most cases the toxicity profile of the herbal medicine especially chronic toxicity data may be lacking which may be interpreted by some regulatory authorities as absence of evidence regarding the safety of the long term use of such products. The processing technology required for the mass production of herbal medicine may be difficult due to peculiar physico-chemical properties of the constituents.

In other to popularise African traditional medicines, we have to accept responsibilities and challenges of conducting controlled clinical trials

with standardised herbal products. The sustainability of producing large quantities of herbal medicines implies that the raw materials (which are plants in most cases) are cultivated preferably ***in situ*** . In view of the fact that the percentage yield of the bioactive extracts are generally very low, it implies that large hectares of land need to be acquired for such cultivation with anticipated obstacles from both government authorities and local communities.

3. PROSPECTS

WHO has defined Good Clinical Practice (GCP)
as standard for clinical studies which encompasses the design, conduct, monitoring, termination, audit, analyses, reporting and documentation of the studies and which ensures that the studies are scientifically and ethically sound and that the clinical properties of the pharmaceutical product (diagnostic, therapeutic or prophylactic) under investigation are properly documented.

Basically, the welfare of the trial subjects as defined in the Declaration of Helsinki should be the primary concern of those involved in conducting clinical trials. In preparing the clinical protocol, the need for a reduced financial component should be borne in mind. In this case, the understanding of the clinicians and biomedical scientists who will be involved in the trial is crucial. The scientist has the responsibility to ensure that Good Laboratory Practice is followed in various experimental procedures leading to the drug product. Both government authorities and local community leaders need to be adequately enlightened about the importance of land needed for *in situ* cultivation of some plant species. In fact, members of the local communities can be

engaged in the cultivation of the designated plants in an environmentally friendly manner. The ladies in the rural communities can be trained in various aspects of post-harvest processing of the desired plant parts. Such a practice will make the local communities to be interested and involved in the whole study with their participation as partners. Economically, it will strengthen their family earnings and improve the opportunities for educating their children. In any clinical trial, the investigators must be ready to take some risks. Such risks however must be sensible. For example, the recipes which have a long history of usage in Traditional Medicine does not need to be subjected to chronic toxicity studies before the commencement of the controlled clinical trials (Phase II). It should also be mentioned that the disease being targeted is very important in making decision regarding clinical trials. Chronic ailments for which there are no effective therapies may require special consideration to facilitate the use of any promising product for such patients who otherwise may die prematurely. For example, it may not be necessary to conduct phase I trial with a promising herbal medicine against HIV/AIDS bearing in mind the mortality and morbidity burdens associated with this epidemic. WHO may prepare model clinical trial protocols for herbal medicines which may be adopted by member countries and used as needed.

4. CONDUCT OF CLINICAL TRIAL

It is assumed that the protocol is prepared stating the purpose of the trial and give a general background to justify the need to conduct the study. Furthermore, the anticipated risks involved should be included in the protocol as well as the criteria for selection of the trial subjects. The

duration of the study, the various laboratory forms, the case report form, consent forms, etc should constitute components of the protocol. As part of the need to protect the trial subjects from known and unknown risks involved in such studies, the provision of the Declaration of Helsinki should be followed strictly. If there is no standing ethical committee in the hospital where the trial will be conducted, an Ad Hoc Committee can easily be established. The patient must be given full information about the study in the language he understands very well. An appropriate consent form should be developed for the study. Such consent form should be written and signed in the presence of witnesses. In the case of a child below 18 years, the mother or father or patron/matron should sign the consent form for the patient/volunteer. The trial subject should be informed that they can withdraw from the trial at any time they want without any penalty whatsoever. Furthermore, they may be given sufficient time to consider whether or not to enroll in the study while allowing them to ask as many questions as they want. There must be sufficient confidentiality of the research data accruing from the clinical study. The trial subjects are entitled to medical care during the period of study and if possible, insurance cover may be considered. The investigators involved in the study should be informed of their immense responsibilities and the need for discipline in the conduct of the trial. The site for the trial should be so chosen where facilities and relevant staff who are willing to participate in the study already exist. The funds required to complete the study should be obtained in full before the commencement of the trial. The data management should be under a biomedical statistician who is conversant with such a study. The design of the trial should be the responsibility of the biomedical statistician which would among others reduce any bias with regards to the randomisation and selection of patients as well as

ensure that the statistical power will enable a reasonable and objective deduction of the difference between the control and treatment groups. The national drug regulatory authority is empowered to provide the legal instruments for clinical trials. The aims of such legal framework include :

i. To protect the safety and right of the trial subjects.

ii. To ensure that trials are adequately designed to meet scientifically objective purposes.

It is appropriate for the drug regulatory authority to review the protocol before the commencement of the trial . It will be ideal to have a mechanism for monitoring the quality and conduct of the trial.

5. WHO MODEL LIST OF ITEMS TO BE CONTAINED IN A CLINICAL TRIAL PROTOCOL

The trial protocol should, where relevant, be required to cover the following points:

- Title and justification for the trial
- Statement of rationale, objectives and purpose of trial
- Brief description of the site(s) where the trial is to be conducted
- Name and address of the sponsor
- Name, address and qualifications of each investigator
- Description of the type of trial (randomised, blinded, open), trial design (parallel groups, cross-over technique), blinding technique (double-blind, single-blind) and method of and procedure(s) for randomisation.

- Description of trial subjects (criteria for inclusion and exclusion of potential subjects), process of recruitment, types, method(s) and timing of allocation of subjects into investigational groups.
- Number of trial subjects needed to achieve the trial objective, based on statistical considerations.
- Description of and justification for the route of administration, dosage, dosage interval and treatment period for the investigational and comparator products, if used. Dose-response relationships should be considered.
- Any other treatment that may be given or permitted concomitantly.
- Clinical and laboratory tests, pharmacokinetic analysis, etc., that are to be carried out.
- Description of how responses are recorded (description and evaluation of methods and frequency of measurement), follow-up procedures and measures to determine the extent of compliance with the treatment among trial subjects.
- Discontinuation criteria for trial subjects and instructions on terminating the whole study or a part of the study.
- Methods for recording and reporting adverse events or reactions, and provisions for dealing with complication.
- Procedures for the maintenance of subject identification code lists, treatment records, lists for the randomisation of subjects and/or case-report forms (CRFs). Records should permit identification of individual patients or participants as well as auditing and reconstruction of data.

- Information about how the trial code is established, where it will be kept and when, how and by whom it can be broken in the event of an emergency.

- Measures to be implemented to ensure the safe handling and storage of investigational and comparator products, if used, and to promote and determine the extent of compliance with the prescribed treatment and other instructions.

- Description of methodology to be used to evaluate the results, (including statistical methods) and to report on patients or participants withdrawn from the trial.

- Time schedule for completion of the trial.

- Information to be presented to the trial subjects, including how they will be informed about the trial, and how and when their consent will be obtained.

- Instructions for staff involved in the trial, including how they are to be informed about the way the trial is to be conducted and about the procedures for drug usage and administration.

- Ethical considerations and measures relating to the trial.

- Medical care to be provided after the trial, modalities of post-trial treatment.

- When the protocol serves as a contract, statements regarding financing, insurance, liability, delegation or distribution of responsibilities, and publication policy.

* List of literature referred to in the protocol.

6. NIPRD EXPERIENCE

In the past 6 years, NIPRD has been involved in the development and preparation of clinical protocols for herbal medicines vis-à-vis their efficacy and safety. As at today, we have developed 6 protocols which are now being used for phases II and III clinical trials of some of the herbal medicines developed at NIPRD. One of such products, NIPRISAN is undergoing Phase III Multicentre Placebo Controlled Randomized Crossover clinical trial in the following University Teaching Hospitals and Reference hospitals:

* University of Nigeria Teaching Hospital, Enugu
* Military Hospital, Yaba, Lagos
* Lagos University Teaching Hospital, Lagos
* Ahmadu Bello University Teaching Hospital, Kaduna
* Military Reference Hospital Kaduna
* University of Maiduguri Teaching Hospital, Maiduguri

The principal investigators at these hospitals are either consultant physicians and consultant paediatricians.

NIPRISAN is a herbal product developed at NIPRD in collaboration with Rev. Ogunyale who gave us the initial recipe for the prophylactic treatment of Sickle Cell Anaemia. The on-going clinical studies will be concluded within the next 9 months which will enable us to register the new product with NAFDAC as an essential drug. Subsequently, NIPRISAN will be prescribed by doctors in Nigieria and included in the National Essential Drug List. The research and development of NIPRISAN was essentially funded by UNDP. They have also paid for the patenting of NIPRISAN in 46 countries in Africa, Asia, Europe, and America. It is anticipated that soon after the registration of NIPRISAN in Nigeria, applications will be submitted to other countries where sickle cell anaemia is endemic especially where NIPRISAN has been already patented.

The phase II clinical trial data of the second herbal medicine (NIFADIN) for the prophylactic treatment of sickle cell anaemia has just been concluded. The results are quite encouraging. Subject to availability of funds, the Phase III clinical trial of NIFADIN may commence before the end of this year.

The clinical trial of the anti-fungal agent (NIPRIFAN) for the treatment of skin fungal infection has been conducted at NIPRD clinic for the past 4 years. It has been found to be very effective agent against fungal infections of the skin. Two anti-ulcer herbal products have also been developed at NIPRD. They have both shown very promising effects during an open phase II study. Furthermore, two drugs have been developed at NIPRD against HIV/AIDS disease. We plan to commence the controlled clinical trial phase II with the two products next month. One anti malarial phytomedicine will undergo Phase II controlled clinical trial next month. WHO has promised to fund the clinical trial of the anti malarial agent. An oral contraceptive from a local medicinal plant has been developed at NIPRD in collaboration with the University of Jos. The clinical protocol is being reviewed by NIPRD Ethical Committee at the moment. After the clearance by the Ethical committee, the Phase III Multicentre clinical trial will commence. For the past 4 years, over 500 ladies have used this new oral contraceptive which is effective for 6 months after a single oral dose. This preparation will be ideal for most ladies, especially those in the rural areas.

Apparently, NIPRD has acquired significant experience in this field. Of course, it wasn't easy when we started the clinical trials of herbal medicines in 1994. We persisted because we believed in what we are doing. It is a case of classical reverse pharmacology.

7. RECOMMENDATIONS

i. We must accept the need to embark upon the clinical trials of herbal medicines as a necessary strategy to make these valuable products available in the national health care system.

ii. The usual "psychological" block which inhibits us from taking a bold step in this direction must be consciously excised.

v. Deliberate efforts should be used to enlighten our colleagues in both orthodox and traditional medical professions so that the biomedical scientists can work with them in the interest of humanity.

vi. WHO has openly challenged us to submit appropriate data which may justify the mass production of any proven herbal medicine in Africa. WHO-AFRO is willing to source for funds and necessary equipment for the mass production of such standardized herbal medicines. We must positively do all we can to respond to this challenge.

vii. The regulatory authorities should be encouraged to assist biomedical scientists in their search for therapeutic agents from local medicinal plants vis-à-vis realistic regulatory provisions without necessarily lowering the standard for the quality, safety and efficacy of herbal medicines.

viii. The private sector has an important role to play in all these endeavours. Generally, the national governments, should support basic research. The private sector should be encouraged to invest in the development of any promising bioactive extract.

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Improving Plant Medicine for Healthcare Delivery in Ghana

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A Paper Presented at the Workshop on "Strategies to Strengthen the Utilization of MAPS in the National Health Care System"

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in Collaboration with

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Abstract

Plant medicine is patronized by majority of Ghanaians, both literate and illiterate, especially, the rural folk who do not have easy access to modern health care facilities. The practice is based on societal beliefs some of which are at variance with science. However, Science can be harnessed to produce effective, safe and quality plant medicines that are universally acceptable because of scientific proof. In view of this, Government of Ghana has enacted laws to facilitate the development of plant medicines with the ultimate goal of its future incorporation into the official health care delivery sytem. The enforcement of the government regulations, the application of science and upholding of proper code of ethics could uplift the practice and quality of plant medicine to meet professional and client expectations, and ultimately facilitate its universal acceptance and incorporation into the National healthcare delivery system.

Introduction

In Ghana, Plant medicine is an important component of the health care delivery system. It caters for the health care needs of a large section of the Ghanaian population. In spite of its wide patronage and immense contribution to health care delivery, it has a number of limitations, which make its official acceptance into the national health care delivery system difficult. The nation recognizes the value and limitations of plant medicine and has earmarked it for improvement in its quality and delivery. This paper outlines some of the measures being adopted to raise the standards of the practice of herbal medicine and herbal medicinal products in Ghana.

Plant Medicine in Ghana

Until the era of colonization, traditional medical practitioners whose methods were holistic provided health care services to the community. Traditional medicine is often based on certain societal beliefs that integrate the social, religious, moral and cultural values of the people (Tse, 1997; Warren, 1986). In Ghana, the practice of traditional medicine may be categorized as follows:

(i) Fetish Priests and priestesses	Healers attached to shrines of a deities who act as a mediums or messengers of the deities
(ii) Traditional birth attendants	Persons who have experience in conducting childbirth
(iii) Bone Setters	Healers who specializes in fractures, using herbs and natural products
(iv) Herbalist	Persons (often illiterate) with knowledge in herbs and natural products and their medicinal uses
(v) Neo-herbalist	Literate or semi-literate herbalists who manufacture herbal preparations and operate in the urban areas.
(vi) Herbalist cum occultists	Persons who employ herbal products and occultism to manage illnesses.

Source: Ghana Human Development Report, 1998

The major part of traditional medicine, however, involves the use of plant extracts or their active chemical components to manage patients. Even practitioners who serve as mediums to

deities of indulge in occultism also use so-called "spiritual herbs" on their patients.

Clearly, the spiritual or psychic aspects of traditional medicine are intangible and most often are at variance with today's science because they cannot be readily verifiable objectively (Archampong,1988). However, the practice of herbal medicine is tangible and is readily amenable to scientific investigations. Unfortunately, the colonialists who were Christians bunched all of the practices together, labelled them as pagan and harmful and therefore, banned them; giving all the practices a negative perception. The introduction of western education also did not help because many educated Africans questioned certain customary practices hitherto unchallenged, thus further worsening the image of all the different practices involved in traditional medicine (Evans-Anfom, 1986).

Driving Issues Behind Policies to Improve Plant Medicine

There is currently a renewed interest in plant medicine and many people, including some highly educated Ghanaians patronize it, especially for management of certain medical cases that allopathic medicine is believed to be ineffective. Many people patronize plant medicine because it is more affordable than allopathic medicine. Others do so because they have no access to modern health facilities.

Some other concerns are the unregulated use of herbal drugs (both in frequency and quantity), self-medication, and difficulties associated with dosage, efficacy, safety and quality of herbal medicines (Batse and Nyarko, 1995); These and the emergence of charlatan herbal medicine practitioners has necessitated improvement and regulation of herbal medicine

Ghana's Traditional Medicine Law

A Traditional Medicine Law has been enacted in Ghana to address some of the above concerns. This law is designed to regulate the practice of traditional medicine. It is consistent with the policy of WHO on the integration of Traditional or Alternate Medicine into national health care delivery systems (WHO, 1976 and 1978). Under the law, Traditional Medicine Practice Council (TMPC) is to be established and charged to set the standards for the practice of traditional medicine in Ghana. Thus a major function of the TMPC is to determine and enforce, in conjunction with recognized association(s) of traditional medicine practitioners, a code of ethics for the practice of traditional medicine.

Other functions of the TMPC are to promote and support training in traditional medicine in educational and research institutions and promote preservation of bio-diversity and large scale cultivation of medicinal plants. (Source: The Traditional Medicine Practice Act, 2000)

The Food and Drugs Board

There is a Food and Drug Law (1992) that mandates operation of the Food and Drugs Board (FDB). It is the FDB responsibility to implement regulatory measures that aim at achieving in Ghana, the high standards of safety, efficacy and quality of food and drugs, including herbal medicines. The FDB thus regulates the registration, advertisement, manufacture, packaging, preparation, labeling, sale, supply, exportation and importation of all herbal medicines. The FDB requires evidence of efficacy and safety from an FDB-certified institution before it approves and registers any plant medicine.

Regulation

In conformity with the laws on traditional medicine and the FDB, the MOH has identified a number of strategies that it would pursue in order to improve the practice of herbal medicine in Ghana. The first of the strategies is the creation of a Traditional and Alternate Medicine Directorate (TAMD) within the Ministry of Health. TAMD is charged to oversee reforms that would develop herbal and alternate medicine in Ghana. Specifically, the Directorate is to coordinate the activities of traditional medical practitioners, and encourage the registration of herbal medical practitioners, identify their training needs and help establish procedures and avenues for research.

Associations of Traditional Medical Practitioners

For effective regulation, the practitioners need to be organized into a body. Although there are six independent associations of traditional medicine in Ghana and each claim to champion the interests of all the others, their activities are uncoordinated as a result of differences in their fundamental beliefs (Evans-Anfom, 1986). As a result it is difficulty on the part of government to deal with the different splinter organizations of traditional healers. These concerns necessitated the formation of The Ghana Federation of Traditional Medicine Association (GHAFTRAM), which is an umbrella association of traditional healers in Ghana. GHAFTRAM is the body currently recognized by government as championing the course of

traditional medical practitioners in Ghana (Source: Nana Ofei Adjentutu II, personal communication).

Plant Medicine Research in the Universities and Research Institutes

In Ghana, Government policy on Plant medicine is improving its quality and delivery and conservation of bio-diversity for its sustained medicinal use. In this regard, research and documentation are paramount. The Universities and research institutes in Ghana are actively pursuing research on several aspects of plant medicine. One institute, the Centre for Scientific Research into Plant Medicine (CSRPM), established in 1975 is specifically charged to conduct and promote scientific research relating to the improvement of plant medicine, and establish, where necessary, botanical gardens for medicinal plants.

The various departments of this Centre, which is a WHO collaborating centre on traditional medicine, apply Science and Technology to produce quality plant medicines at the Centre. Good Laboratory and Manufacturing Practices (GLP & GMP) is core to the activities of the Centre. For example, the Centre through its relevant departments or with the collaboration of scientists at the Universities, investigates the efficacy and safety of its products. It pays particular attention to producing quality products. It therefore, has in place a process of standardization from the point of raw material collection and sourcing, through processing to the final preparation. In order to improve shelf life, the Centre is formulating some of its decoctions into other dosage-forms like tablets, capsules and suppositories. The Centre operates an outpatient clinic where limited clinical evaluations, including dose-range studies of the herbal medicines are performed after the preparations have undergone pre-clinical safety evaluation in animals. Currently the CSRPM is a WHO collaborating Centre on plant medicine research

In addition to its research activities, the CSRPM trains herbalists on aspects of standardization and production of quality plant medicines and conducts safety evaluations for herbalists upon request.

The Universities and other Research Institutes are contributing to research and development of herbal medicine. However, the research efforts are uncoordinated, thus, the public does not

realize their impact on the practice and use of plant medicines. For example there is active on-going characterization and documentation of plant medicines (Abbiw, 1990; Ghana Herbal Pharmacopoeia, 1992). Some chemists and pharmacognosists are also pursuing phytochemical characterization of medicinal plants (Addae-Mensah, 1989). Other researchers who have biomedical interests focus on research that aims at validating the medicinal value and safety of plant medicines (Addy and Schwartzman, 1995; Nyarko and Addy, 1994; Nyarko *et al.* 1993 and 1999, Noamesi and Bangbose, 1981). Social science research is elucidating the integrative function of traditional medicine to the Ghanaian society (Tse, 1997)

Future Direction

Currently, traditional medical practitioners are allowed to practice in Ghana. There is the possibility it being incorporated into the official healthcare delivery system. It is not very clear yet whether when the time comes traditional and modern medicine would be integrated or set to run in parallel (Bodeker, 1994). Whatever the case a number of issues need to be addressed before embarking on any form of incorporation of traditional medicine into the national health care delivery system. These include:

- Education and training of practitioners to upgrade their knowledge and skills
- Validation of the efficacy and safety of plant medicines
- Improving the quality and determination of efficacious and safe dosages of herbal medicines
- Educating the public to accept only certified plant medicines
- Conservation and sustained use of bio-diversity for medicinal purposes
- Promotion of ethics in plant medicine
- Educating practitioners and the public on intellectual property rights
- Intensification of monitoring and evaluation of the practice and products of plant medicine.

Scientific validation of the efficacy and safety of plant medicines, determination of their pharmacological/physiological effects, safety assessment and documentation of possible side/adverse effects of plant medicines would enable informed choices to be made during patient management with plant medicine for better health care. Similarly, the current procedures used by herbalist to manufacture their preparations would require scientific investigations and

quent standardization in order to evolve optimum conditions that could ensure good results.

clusion

if research into the efficacy and safety of medicinal plants, and the application of ved technology would add value and probably cost to the plant medicines, improve their y and enable their rational use for their full benefits to be realized by all who need or use is a fact that medicinal plants have since time immemorial played key roles in the ion of health to humans (Lewington, 1990). A number of drugs: aspirin and codeine, ine, reserpine and, quinine and artemisinin that are used in modern medicine today are d from plants (Farnsworth, 1985). Therefore, science-led improvement in the quality of medicines can bring relief for many people who cannot afford have little or no access to health facilities

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Approaches pursued in South Africa to strengthen utilisation of Medicinal Plants and Traditional Medicine Health Care System

Efforts pursued to strengthen the utilisation of medicinal plants and traditional medicine in the National Health Care System in South Africa occur at government and non-government (Health Product Association, Traditional Medical Practitioners Associations and Consumers through Trade Unions) levels. The nature of activities are overt at government level and both overt and covert at non-government level. This paper will focus at critical elements that serve as indicators in the process of strengthening medicinal plants and traditional medicine utilisation in the National Health Care System. Deficiencies and factors that contribute to limit efforts that are pursued will be stated with the intent of highlighting them as areas that need to addressed as strategies to strengthen traditional medicine in national health care system.

The following critical elements will be looked at: policy or legal framework for the utilisation of traditional medicine of plant origin; appropriate structures and legislation for traditional medicine / medicinal plants; regulatory framework for the registration of traditional medicines of plant origin; research into traditional medicines (of plant origin); policy or legal framework for the practice of traditional medicine; and integration of traditional medicine in the health system; mechanisms for collaboration between health care providers and other stakeholders; deficiencies and needs with respect to traditional medicines (of plant origin);

GOVERNMENT EFFORTS

I. POLICY OR LEGAL FRAMEWORK FOR THE UTILIZATION OF TRADITIONAL MEDICINES OF PLANT ORIGIN

The Department of Health National Drug Policy for South Africa stipulates investigation of the use of effective and safe traditional medicines at primary level. It calls for: the investigation of traditional medicines for efficacy, safety and quality with the aim of incorporating their use in the health care system, the registration and control of marketed traditional medicines, and provisions to establish a National Reference Center for African Traditional Medicines (NRCATM).

II. APPROPRIATE STRUCTURES AND LEGISLATION FOR TRADITIONAL MEDICINE / MEDICINAL PLANTS

The establishment of a National Reference Center for African Traditional Medicines has been approved by the National Minister of Health. A post has been advertised for a person who is to coordinate the activities of the Center.

The format of the of National Reference Center of African Traditional Medicines include some of the following features:

A. Functions

- development of a national database of indigenous plants that have been screened for efficacy and toxicity
- testing of toxicity and efficacy
- compiling a national formulary of Medicines Control Council approved "essential traditional medicines"
- Propagation of medicinal plants

B. Objectives

The objectives of the National Reference Center for African Traditional Medicines are:

Primary Specific Objectives

- To put in place an appropriate and practical regulatory framework for the registration, regulation, control and development of African Traditional Medicines by utilizing information generated from research into traditional medicines.
- To establish a database with emphasis on information technology.
- To promote research and development with a bias on aspects of standardization and authentication of products from plant extracts of African Traditional Medicines using the guidelines published by the World Health Organization.
- To identify the education and training needs in Traditional Medicine in South Africa.
- To address indigenous/traditional knowledge matters with respect to African Traditional Medicines.
- To address the issue of sustainability and conservation by promoting cultivation of medicinal plants.

Other Specific Objectives

- To encourage the exploitation of existing research findings with the view of bringing them to the use of the people, through local production of simple, affordable formulations of effective and safe medicinal plants in standardized forms (e.g. standardized teas, powders, simple extracts, etc.)
- To identify priority research particularly related to HIV/AIDS and common diseases prevented and treated by African Traditional Medicines.
- To foster and identify areas of collaboration in African Traditional Medicines research amongst research institutions, researchers, parastatals, traditional healers associations, non-governmental organizations, and government departments. To stem the element of duplication of efforts.
- To come up with a policy that recognize, promote and rehabilitate African Traditional Medicines prevalent in South Africa and maximize their utilization in health teams to address national health care needs of the country.
- To facilitate obtaining maximum returns for money invested by the government, through various departments, in African Traditional Medicines research.

C. Strategy

The strategy involve, inter alia, the following approaches:

1. Pulling together various stakeholders involved in African Traditional Medicines research activities. The stakeholders will be approached to participate as partners in the activities of the National Reference Center. The National Reference Center will be multidisciplinary. Government Departments are included amongst stakeholders because they are involved either directly or indirectly in African Traditional Medicines activities through funding some of the other stakeholders.
2. Coordinating the activities of the identified government departments that fund research into African Traditional Medicines.
3. Establishment of communication net work amongst government departments, research institutions, traditional healers, researchers, parastatals, traditional healers associations, and non-governmental bodies involved in African Traditional Medicines.
4. Establishing external links with the following bodies so as to address and include the global aspects of traditional medicines.
   - World Health Organization - African Region
   - World Health Organization - Head Quarters: Geneva
   - Food and Agricultural Organization

D. Participants

The partners to be involved in the National Reference Center for African Traditional Medicines activities are:

Governmental Departments

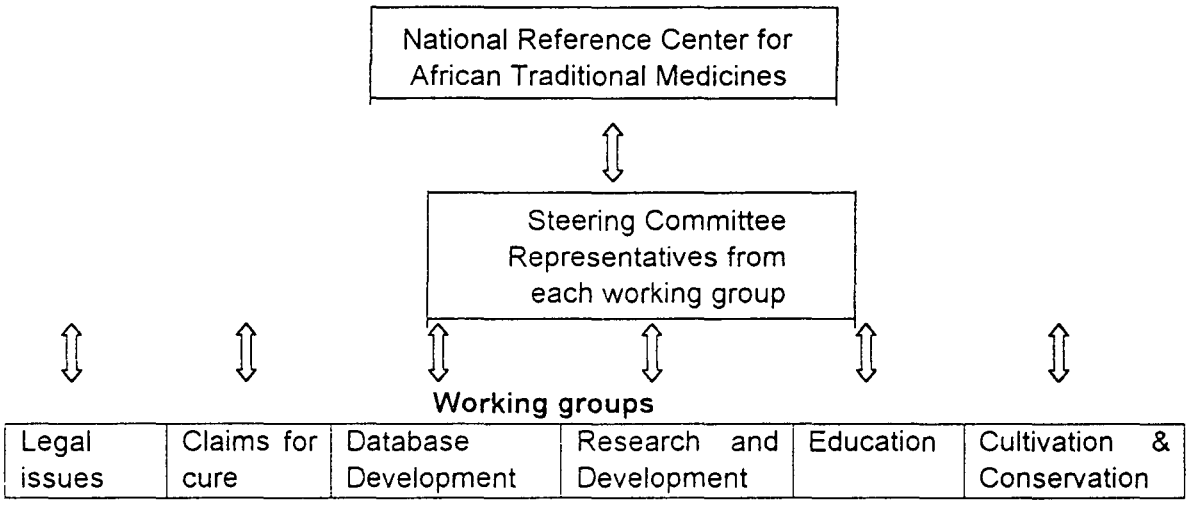
1. Department of Environmental Affairs and Tourism,
2. Department of Agriculture,

3. Department of Arts, Culture, Science and Technology.
4. Department of Water Affairs and Forestry
5. Department of Education
6. Department of Trade and Industry

- ***Parliamentary Interventions/Inputs***
- ***Other Stakeholders***

1. Universities
2. Parastatals
3. Statutory Councils
4. Research Institutions
5. Non Governmental Organizations
6. Traditional Medical Practitioners
7. Traditional Practitioners Organizations

E. National Reference Center Structure



Two representatives from each working group will constitute the Steering Committee.

III. Regulatory framework for the registration of Traditional Medicines

The regulatory framework for registering traditional medicines is done under the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965). A special expert committee of the Medicines Control Council named 'African Traditional Medicines Committee' is being established. This expert committee function will be to evaluate applications to register traditional medicines (of plant origin).

IV. Policy or legal framework for the practice of traditional medicine

The working groups of the National Reference Center for African Traditional Medicines together with the expert committee on African Traditional Medicines would be tasked to look at mechanisms of promoting and rehabilitating traditional system medicine and to develop a policy that will maximize traditional medicinal plants utilization in health system.

V. *Integration of traditional medicine in the health system*

The matter will be addressed by the National Reference Center for African Traditional Medicines and will be linked to the issue of intellectual property rights in traditional medicine.

VI. *Research into traditional medicine*

Research activities into African Traditional Medicines by various parties will be harmonized through the National Reference Center for African Traditional Medicines. The NRCATM will encourage Center institutions involved in research on traditional medicine(s) to disseminate information and to promote use of research findings. The research findings would be brought to the use of the people through production of simple formulations of effective, safe medicinal plants in standardized form (e.g. standardized teas, powders, simple extracts, etc).

VII. *Mechanisms for collaboration between health care providers and c stakeholders*

Mechanisms that permit firm cooperation between traditional practitioners, scientists, orthodox medi practitioners, and other health care providers with acceptable arrangements for a better and loyal collaboration exist through advocacy programmes such as the HIV/AIDS advocacy programme. Structures such as the South African National AIDS Council and the National Reference Center for African Traditional Medicines caters for multi disciplinary cooperation, collaboration and interaction between different health care providers.

NON GOVERNMENT EFFORTS

Efforts to strengthen utilization of traditional medicinal plants in national health care system comes various quarters such as Trade Unions, Traditional Healers Association), private citizen and industr produce complementary medicines.

Trade Unions

Members of Trade unions are pressurizing their employers to accept Traditional Medical Practitioner leave certificates. They are also pressurizing the medical aid scheme to cater for the services provid traditional medical practitioners with their medicines.

Traditional Healers (Associations)

The traditional healers (associations) are continuously advocating and approaching the governm establish a Traditional Medical Practitioner's Council (TMPC). The TMPC existence will facilitat utilization of traditional medicinal plants and the integration of traditional medicine system into the na health care system.

Private Citizens

Private South African citizens have banded together to form joint venture companies that concentra research and development of African Traditional Medicinal Plants. They produce standardized med plant products and nutraceuticals that have scientific research backing. The products are produc adhering to sustainable conservation methods and good manufacturing procedures, and are harv according to good agricultural procedures. They produce quality products at affordable cost t consumer, traditional medical practitioners and other health care providers.

Industry in Complementary Medicines

The other sector that contributes to the movement of keeping medicinal plants on the attention of t government is the constituency or industry that deals with the manufacture and importation complementary medicines. This sector continuously petition the government to establish registration a regulatory framework that cater for complementary medicines, which also includes medicinal plar products.

Conclusion

The strategy of strengthening utilization of traditional medicinal (aromatic) plants in national health system is a process and endeavor that should not only focus on the above stated critical elements but it should also deal with the deficiencies and needs with respect to traditional medicines (of plant origin), and other contributing factors.

The strategy will be to turn the deficiencies, gaps and need into positive outcomes that should communicated and made available to the consumers of traditional medicinal plants, practitioners traditional medicine and other health care providers in the national health system. Some of the deficienc: gaps and needs are:

- The lack of local production of traditional medicines that meets the needs of local population, traditic medical practitioners and institutions;
- The need to transform research results on traditional medicines into production of safe, efficacio standardized (improved) and affordable traditional medicines;
- The need for intellectual property rights regimes to deal with and protect the unique situatior traditional medicine knowledge and traditional medicines;
- The need for the establishment of an essential drug list that includes traditional medicines.
- The need for national pharmacopoeia on medicinal plants like the Ayurvedic Pharmacopoeia of In

The other contributing factors that need to be considered include amongst other things: use of organized traditional medicine systems like Ayurveda from India as models that have been utilized successfully in their national health care system; fostering of regional and sub-regional exchanges on Traditional Medicine; institution of Traditional Medicine Day; involvement of the private sector in the deve!opment process of local production of traditional medicines; encouragement of scientists write books for didactic work on traditional medicine; establishment of Centers of excellence to determine the safety and efficacy of traditional medicines; The development of capacity for research into aspects of standardization, authentication and integration of traditional medicines into the health system; production of improved and standardized African Traditional Medicines that meet the needs of local populations, traditional medical practitioners and institutions.

PROMOTING THE USE OF TRADITIONAL HERBAL MEDICINE IN THE NIGERIAN HEALTH CARE SYSTEM

Paper Presented by

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At The Workshop on

Strategies to strengthen the Utilization of MAPs the National Health Care System

Organised by

ICS-UNIDO

in Collaboration with NIPRD, Abuja.

11-13 July, 2000

GLOBAL TRADITIONAL MEDICINE RENAISSANCE

- Despite prolonged neglect and conflict wit orthodox medicine, there is renewed intere in traditional medicine globally.

- While it offers choice and esoteric interest the industrialized countries it is still the mainstay of health care for a majority of th populations of developing countries.

- TRM enjoys wide popularity - simple, culturally acceptable and the practice is wholistic

- Economical to develop new drugs

- Politically correct because of proportion o the national populations depending on it

- TRM practitioners are available at the grassroots.

USE OF TRADITIONAL HERBS STILL MINIMAL IN THE FORMAL HEALTH CARE SYSTEM IN NIGERIA

- Emphasis on Formal health care system/services – public sector, religious, voluntary organizations & private sector

- Some use of herbal medicines from foreign countries in the private sector services in recent years – but still minimal

- No reliable data on use of Nigerian traditional herbs, but believed to be highly prevalent

TO PROMOTE USE OF TRADITIONAL HERBS

- Same strategies as promoting TRM

A. CONCEPTS

- TRM should be conceptualized beyond medicine/drugs

- TRM is body of knowledge + Practices that have evolved from customs and tradition

- So there is mystic unity of practice (e.g. herbal medicine) and Practitioner

- Some demystification necessary or skill articulation and transfer will be impossible

TO PROMOTE TRADITIONAL MEDICINE

B. POLICY RELATED STRATEGIES

- Regulation – of traditional medical practitioners: of the health care system: and of traditional medicinal products.

- Regulation of traditional medicinal products – manufacture, import, export, dispensing, trade utilization, etc

- Conservation of Medicinal Plants used in TRM

- ETC

TO PROMOTE TRADITIONAL MEDICINE

C - OPERATIONAL STRATEGIES

- Standardization and Quality Control of Herbal Medicines (* very relevant to this workshop)
- Selection of a list of Essential Herbal Medicines
- Training of Present and Future Practitioners
- Establishing Intellectual Property Rights of Practitioners
- ETC

TO PROMOTE USE OF TRM

D - DEVELOPMENTAL STRATEGIES

- Development of a National Traditional Medicine Information System

- Establishment of Model Institutions and Services – Clinics, Training Schools, Botanical Gardens, Manufacturing Units etc

- National TRM Network + Newsletter

- Articulation of a National TRM Development Agenda by all stakeholders and role players – in consonance with WHO's strategy for the African Region

- Documentation of TRM as a body of knowledge

- The NTMDP must be as inclusive as possible

WHAT HAS THE NATIONAL TRADITIONAL MEDICINE DEVELOPMENT PROGRAMME DONE SO FAR?

- Established in 1997
- National Technical Working Group on TRM established
- Policy Documents Articulated
  - Broad Policy
  - Code of Ethics
  - Draft decree for Federal Traditional Medicine Board (being Re-processed)
  - Draft Edict for State Boards on TRM
- Minimum Standards for TRM Practice in Nigeria established
- Curricula developed for Training in TRM – Diploma Courses in Traditional Herbal Medicine; Herbal Medicine Ingredient Selling; Traditional Bone Setting; Traditional Mental Health and Traditional Birth Attendance

CONCLUSION

- TRM used to be the sole method to health care before the advent of orthodox (Scientific) medicine
- Renaissance of TRM would also require a system wide approach
- This is not to say that any group of role players must wait until all the proposed strategies have been implemented or every citizen has become a TRM enthusiast
- What is required is that progress must be made along different Strategies. BUT all role players should understand and appreciate the common Goal and Agenda and continually work towards achieving them
- In this regard, the organizers of this workshop deserve our sincere commendation

THE INEGRATION OF TRADITIONAL AND MODERN MEDICINE IN THE UTILISATION OF MAPs IN THE NATIONAL HEALTH CARE SYSTEM

PRESENTED IN

INTERNATIONAL WORKSHOP ON
"STRATEGIES TO STRENGTHEN THE UTILISATION OF MEDICINAL AND AROMATIC PLANTS IN THE NATIONAL HEALTH CARE SYSTEM"

ABUJA, NIGERIA (11 - 13 JULY 2000)

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THE INTEGRATION OF TRADITIONAL AND MODERN MEDICINE IN THE UTILIZATION OF MAPS IN THE NATIONAL HEALTH CARE SYSTEM

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THE INTEGRATION OF TRADITIONAL AND MODERN MEDICINE IN THE UTILIZATION OF MAPS IN THE NATIONAL HEALTH CARE SYSTEM

INTRODUCTION

Traditional Medicine in Tanzania is as long as the mankind and its practice by a traditional healer has existed that long. Traditional systems in general have had to meet the needs of the local communities of many countries including Tanzania. Most of the populations in various developing countries around the world depends on traditional medicine for primary health care, that the workforce represented by practitioners of traditional medicine is potentially important resources for the delivery of health care and that medicinal plants are of great importance to the health of individuals and communities.

Currently, it is estimated that there are about 75,000 traditional healers in the whole country of Tanzania, which exemplify a ratio of 1:320 compared to the conventional doctors/patient ratio of 1:20,000. Of this great workforce overhalf of them are general practitioners known simply as "herbalist" who deal with common health illness. Others are "bonesetters" and "TBAs". In most parts of the country, TBAs are the ones who are responsible for all problems of Gynaecological, obstetrical and Neonatological aspects. Many patients, currently estimated at over 60% of health care seeking population have a traditional healer as the first point of contact. Lack of essential drugs in rural health facilities plus economical constraints and lack of transport measures in rural areas forces a large number of health care seeking population to attend to a traditional healer.

RATIONALE FOR THE INTEGRATION

Tanzania and probably the whole continent of Africa, many health problems such as malaria, Diarrhoea, schistosomiasis, HIV/Aids, Tuberculosis and acute respiratory infections. The fight against these diseases require the discovery and use of medicines and/or vaccines. Those medicines and vaccines are daily becoming more and more expensive for Africa, while the resources for health in Africa are becoming progressively less. To make matters worse, microorganisms causing these diseases are progressively developing resistant to current drugs for example, plasmodia falciparum

resistance to chloroquine. However, Africa has aoundant resources for the treatment of various diseases including malaria. These traditional medicines exist in various forms such as herbs or plants, minerals and fungi products. The knowledge of traditional medicine has always been passed on from one generation to another through verbal communications under the restricted community customs and norms. Due to these customs and norm, the knowledge is limited to few people in every community hence limiting its development. As a result, the traditional medicine development has not been following the scientific approach and has been retaided. This is the main reason for the existing gap between modern and traditional medicine. In the absence of strategies for systemic and scientific development and use of traditional medicines, in a modern and presentable way, the knowledge will face a great risk of being lost through natural deaths of the traditional medicine practitioners.

METHOD OF INTEGRATION

In order to have a better management of the development, use and conservation of this enormous wealth of existing medicinal sources, modern scientist of Africa should find all possible modalities of integrating the two systems. African scientists should see other countries like China, who has managed to develop and integrate their traditional medicine practice through research. There are various "model" of developing and integrating traditional medicine into the National Health Care System. Among all, the successful nations have found that, it is only through the traditional model method which showed and in fact proved successful in researching, promoting and later integration of traditional medicine into the National Health Care Systems.

The traditional model method has five stages:-

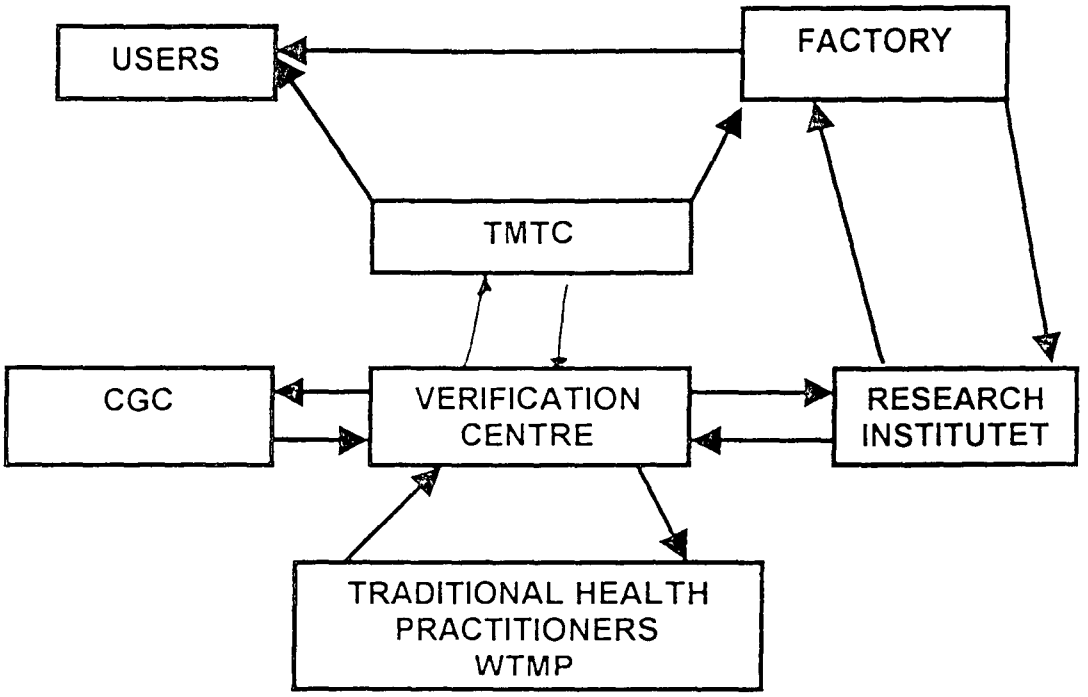
⇒ <u>The traditional health practitioner and the community</u>: This is the first stage of a traditional model. A traditional health practitioner lives in a community of people where he/she is practicing. People in the community including leaders and elders are fully aware of who is a real traditional health practitioner and who is not. Effort should be made to document most if not all of the work practiced.

⇒ Verification centers (Clinical research centers):
This is the second stage of the model, whereby all the documented information is approved through clinical research following assurance, that there is no harm from the applied procedure(applied drug) i.e. toxicologically safe.

⇒ Research Institute:
This is the third stage of a traditional model. It is here where a full flagged research is done, including:

- Ethnobotanical studies
- General and isolative chemical analysis
- Crude extraction
- Small scale drugs production
- Data bank formulation
- Herbarium and museum formulation etc.

⇒ Pharmaceutical factory:
This is the fourth stage of a model, it is here where drugs (medicines) are being processed and produced in a modern or presentable form.



- CGC = Chief Government Chemistry
- TMTC = Traditional Medicine Training Centre
- WTMP = Western Trained Medical Personnel

⇒ Users

This is the sixth stage of traditional model. This is the area whereby prepared drugs (medicines) will be prescribed and or sold in a health institutions including pharmacy.

CONCLUSION

Traditional health practice is here to stay no matter effort to promote it do exist or not. It is also true that there is no longer any doubt about the value of incorporating traditional medicine into modern health care. It is happening for many reasons but, basically because people believe that traditional medicine practices have value that they are willing to subscribe to.

What is still unclear is how modern scientists will transform themselves to suit the integration of the two systems.

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