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Bioprospecting and Strategies for Industrial Utilization of Medicinal and Aromatic Plants

Report of a workshop sponsored by the International Center for Science and High Technology (ICS) Trieste Italy, Bioresources Development and Conservation Programme (BDCP) and United Nations Industrial Development Organization (UNIDO) held at Nike Lake Resort Hotel, Enugu Nigeria on September 21-27, 1997.

Maurice M. Iwu and Elijah Sokomba
Bioresources Development and Conservation Programme
110 Aku Road, P.O. Box 3138, Nsukka Nigeria

October 22, 1997

EXECUTIVE SUMMARY

Industrial utilization of biological diversity has been recognized as a feasible way of adding value to forest resouces. For developing countries, it has become crucial to develop mechanisms for safeguarding a resource that meets the basic needs of their people without compromising the well-being of future generations and the integrity of the environment. As several developing countries adopt the western style free market system and political pluralism, the interaction between economic needs and the requirements for conservation becomes even more demanding, complex and urgent. It is this understanding that informed the United Nations Conference on Environment and Development which produced the Convention on Biological Diversity (CBD). The Convention, which has been ratified by 166 nations, provides a framework for the exchange of genetic materials and the equitable distribution of the benefits arising from the commercialization of biodiverstiy. As the international community marks the 5th year of the Earth Summit, it has become obvious that a huge gap exists between policy-level debates and the practical implementation of the tenets of the CBD. Scientists and scholars in developing countries who are expected to provide the necessary linkage between concepts and practice are often not privy to much of the discussions concerning bioprospecting. In most cases they even lack the necessary information or data to give any serious advice to their home governments.

It is now widely accepted that drug discovery programs based on natural products offer one of the most econmically viable approaches to increase the net worth of forests. Due to their high degree of biological diversity, tropical forests hold the greatest promise in the search for new drug molecules. A recent survey of the number and sources of anti-cancer and anti-infective agents developed as new drugs for the period 1989-1995 showed that over 60% of the approved drugs and pre-NDA candidates are of natural origin. A commercial evaluation of the best selling pharmaceutical agents showed that nearly half of the drugs in that category were either natural products or their derivatives. An earlier analysis of the U.S. National Prescription Audit data for the 15-year period from 1959 to 1973 reported that over 25% of U.S. prescription drugs were derived from plant products. Perhaps, of particular interest is the fact that 119 compounds of significant clinical importance are derived from 90 plant species and that 77% of these are from plants used in traditional medicine. The fact that traditional medicinal agents possess observable pharmacological activities and contain compounds with very impressive biological activity with good pharmacokinetics profile does not necessarily mean that such materials could easily be transformed into pharmaceutical agents. The decision to develop a given compound as a product of drug discovery to a commercial dosage form does not depend only on logical scientific criteria. In most real life situations, the decision is based on corporate strategic interests and other commercial concerns that may not be related at all to the scientific/medical merit of the discovered active molecule. Developing countries scientists and institutions interested in entering into biodiversity commercial business or collaboration with the private sector should have some insight on the determinant factors that govern the selection of candidate material for development as a drug.

Issues identified as very crucial for sustainable commercialization of biological diversity include:

- How to deal with policy considerations at the interface between ownership and access of genetic materials and at the same time addressing the dynamic relationship between valuation and equitable distribution of benefits arising from the commercialization of genetic resources. How should investigators compensate indigenous communities for the contribution of local knowledge to the development of genetic resources as marketable consumer goods? While establishing benefit sharing schemes it is essential to ensure that traditional systems and cultures are not disrupted by the wholesale importation of concepts and methods from outside, no matter how seemingly benevolent or well intentioned. Local knowledge should be geared to local self-reliance, equitable distribution and access to resources and local capacity and institution building.
- Establishment of the commercial arrangement that is best suited for the peculiarities of multi-ethnic nations with large populations of indigenous communities and even the special needs of individual countries. In other words, should developing countries provide access to their genetic materials

through research agreements which provide for fixed one-time cash payments (as in the sale of automobiles) or enter into strategic alliances with private and commercial organizations for mutually beneficial programmes for the commercialization of biological resources? What level of value should be added at the source nation before the genetic materials are exported?

- Whereas these issues are subjects of constant debate in industrial countries and international seminars and have indeed produced a plethora of interesting and highly informative literature, much progress has not been made in assisting developing countries to articulate workable policy models on bioprospecting. Several examples of on-going bioprospecting projects (such as the U.S. NCI natural products programme, Shaman Pharmaceuticals ethnobotanical based drug development programme, the International Cooperative Biodiversity Group (ICBG) projects, the INBio bioprospecting programme and the integrated biodiversity development projects by BDCP) are now available which make it possible to learn from the experiences of others and to establish better programmes that are specifically designed to meet the needs of particular countries.
- Establishment of adequate and sustainable technological platforms in biodiversity rich countries to enable them add value to their genetic resources through material processing and product development

In order to provide practical solutions to the above issues, the International Centre for Science and High Technology (ICS), an autonomous institution within the legal framework of the United Nations Industrial Development Organization (UNIDO) conducted an International Training Workshop on "Bioprospecting and Strategies for Industrial Exploitation of Medicinal and Aromatic Plants" at Enugu Nigeria (September 22-27, 1997) in collaboration with the Bioresources Development and Conservation Programme (BDCP).

Workshop Objectives

- To train mid-level, scientists as well as institution and private sector managers with biology/chemistry/pharmacognosy background on the key elements in establishing bioprospecting programmes, in revising practical issues for the commercialization of biological resources and related technologies for the industrial exploitation of medicinal and aromatic plants.
- To identify potential focal points for the UNIDO-ICS network of biodiversity prospecting for industrial promotion and business development.
- To review, assess and collect updated information on projects, methodologies, applied technologies, economic factors for the development of biodiversity prospecting programmes and initiatives.

Deliberations at the Workshop

Following the opening ceremony, the workshop commenced by reviewing the global perspectives of bioprospecting. The role of The International Center for Science and High Technology (ICS) [an agency within UNIDO] in the development and application of science and technology for industrialization was discussed in relation to bioprospecting for pharmaceutical and related industries. Industrial exploitation of medicinal and aromatic plants is intricately related to the overall development and environmental policies of a country. Furthermore, the sustainability of industrial production is dependent on the availability of raw materials. Bioprospecting, therefore, is a necessary activity undertaken to formulate a national plan for industrial exploitation of the plants. Bioprospecting is not only a screening activity for genes, species and ecosystems but also an activity evaluating the sustainability of industrial exploitation of these resources. The role of agrotechniques for domestication and propagation and of biotechnology for assisting in the production of raw materials and products must be examined carefully and taken into consideration. National policies for development of rural areas have to be reviewed in light of the fact that medicinal and aromatic plants are of great importance in health systems of these areas as well as having a high potential in international trade.

Three key issues were discussed:

- In-country research and development through cooperative agreements, involving capacity building, collaboration and partnerships, and strategic business alliances.

- Acquisition or transfer of appropriate technology for materials processing and Product development.
- International Bioprospecting Arrangements.

Unfortunately, while bioprospecting per se has been addressed to some extent, little or nothing has been done for the other two concerns. With regard to bioprospecting, it was noted that there were three key points that required attention:

- Sustainable sources of raw materials.
- Material processing.
- Benefit sharing agreements.

Subsequent discussions addressed other issues such as intellectual property rights (IPR), ownership and commercialization of medicinal and aromatic plant products and their processing. It was stressed that laws are dynamic and not static, biodiversity legislations should therefore not be too restrictive by attempting to cover and anticipate all possible and immaginable future scenerios. Particular emphasis was placed on laws relating to IPR and patents. A review of the existing legislation revealed that most African countries do not have appropriate laws to cater to the provisions of the Convention on Biodiversity (CBD), including bioprospecting. It was pointed out that individual countries should be encouraged to take legislative measures that will create an enabling environment for sustainable utilization of their biodiversity, such as strengthening IPR laws. Harmonization of such laws within the continent is necessary for a common regional position on the management of Africa's biological and ecological resources. It was noted with concern that most laws in Africa tend to be punitive. In order to encourage community participation in this endeavor it is necessary that the laws should be formulated after a transparent and participatory discussion with all stakeholders and incentives should be provided.

Country reports and projects were presented and discussed. These included reports from Cameroon, Ethiopia, Gambia, Ghana, Guinea, Kenya, Madagascar, Mali, Nigeria, South Africa, Uganda and the United States of America. It became apparent that in all countries there is a need to encourage involvement of universities and research institutions. This will ensure that the necessary knowledge required for the conservation and sustainable utilization of biodiversity is available. Standardization of phytomedicines is necessary for quality control, process control, dosage and the law. The relevance of producing official herbal monographs and compendia such as those in the U.S. Pharmacopoeia and the African Pharmacopoeia was highlighted. The workshop concluded with a visit to the BDCP Center for Medicinal and Aromatic Plants at Nsukka. The resource center which was established with support from Shaman Pharmaceuticals Inc and the International Cooperative Biodiversity Group programme has facilities for processing and documentation of medicinal and aromatic plants. The services provided by the center include contract bioasssays, production of extracts and maintenance of an extract library, analytical quality assurance support to local biopharmaceutical and cosmetic industries, reference herbarium and library, and training programme on various aspects of biodversity conservation and sustainable use of natural resources.

Main Recommendations:

- The service coverage of the ICS/UNIDO should be expanded to include pro-active capacity building and technology transfer in the field of industrial utilization of medicinal and aromatic plants.
- African countries must enact, as matter of urgency, appropriate and adequate legislation that would be conducive to conservation and sustainable utilization of their biodiversity. Emphasis should be laid on enforcement of these laws.
- The workshop recognizes the important role of the Scientific, Technical and Research Commission of the Organization of African Unity (OAU/STRC). The workshop thus strongly recommends that the role of OAU/STRC should be strengthened with the expressed aim of formulating a harmonized and enforceable African position on conservation and sustainable utilization of biodiversity.
- African countries must take urgent action to ensure adequate capability and capacity of human resources. A particular effort must be made towards increasing public awareness on the importance of medicinal plants and their conservation and training or mounting public enlightenment

programmes within the local population to recognize IPR issues. This is especially true for the direct users such as traditional medical practitioners, scientists and institutions, national agencies and industry. Concise national patent information policies should be formulated.

- Models of various aspects of bioprospecting including benefit sharing and commercial arrangements (such as the Shaman Pharmaceuticals partnership arrangements with indigenous communities, the U.S. NCI plant collection agreements, the International Cooperative Biodiversity Group (ICBG) prjects, INBio bioprospecting programme and the BDCP community based projects in various parts of Africa) should be studied during the process of developing national policies on conservation and sustainable utilization of biodiversity.
- The workshop notes with great concern the lack of facilities for carrying out standardization and toxicological evaluation of medicinal and aromatic plants in Africa. The workshop thus strongly recommends that multilateral institutions such as the United Nations Industrial Development Organization, the Global Environmental Facility and OAU/STRC should find mechanisms to rectify this situation.
- Recognizing that a considerable number of medicinal plant products in various formulations are already available in the market and are in general use, the workshop strongly recommends that such medicines and preparations should be standardized in the shortest possible time.
- The workshop noted with great appreciated the efforts of the Bioresources Development and Conervation Programme (BDCP) in training and capacity building in many African countries and recommends that the organization should be assisted to extend its intermediary role to other African countries not yet covered and if possible to other developing countries in Latin America and Asia.

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The Book of Proceedings is incorporated as an attachment to this report.

I. INTRODUCTION

Efficient management and sustainable use of genetic resources have become essential elements in the socio-economic growth of developing countries. These genetic resources have been valuable sources of food, building materials for houses and medicines for rural communities in developing countries. The depletion of plant genetic resources threatens the way of life of a large segment of human population. It is now widely accepted that careful use of these resources can lead to poverty alleviation, improvement in quality of life, improved food security and energy needs, while at the same time creating incentive for the conservation of biological diversity. For individual countries, it has become crucial to safeguard a resource that meets the basic needs of their people without compromising the well-being of future generations and the integrity of the environment. As several developing countries adopt the western style free market system and political pluralism, the interaction between economic needs and the requirements for conservation becomes even more demanding, complex and urgent. It is this understanding that informed the United Nations Conference on Environment and Development which produced the Convention on Biological Diversity (CBD). The Convention, which has been ratified by 166 nations, provides a framework for the exchange of genetic materials and the equitable distribution of the benefits arising from the commercialization of biodiverstiy. As the international community marks the 5th year of the Earth Summit, it has become obvious that a huge gap exists between policy-level debates and the practical implementation of the tenets of the CBD. Scientists and scholars in developing countries who are expected to provide the necessary linkage between concepts and practice are often not privy to much of the discussions concerning bioprospecting. In most cases they even lack the necessary information or data to give any serious advice to their home governments.

It is now widely accepted that drug discovery programs based on natural products offer one of the most feasible approaches to increase the net worth of forests. Due to their high degree of biological diversity, tropical forests hold the greatest promise in the search for new drug molecules. A recent survey of the number and sources of anti-cancer and anti-infective agents developed as new drugs for the period 1989-1995 showed that over 60% of the approved drugs and pre-NDA candidates are of natural origin. A commercial evaluation of the best selling pharmaceutical agents showed that nearly half of the drugs in that category were either natural products or their derivatives. An earlier analysis of the U.S. National Prescription Audit data for the 15-year period from 1959 to 1973 reported that over 25% of U.S. prescription drugs were derived from plant products. Perhaps, of particular interest is the fact that 119 compounds of significant clinical importance are derived from 90 plant species and that 77% of these are from plants used in traditional medicine. The fact that traditional medicinal agents possess observable pharmacological activities and contain compounds with very impressive biological activity with good pharmacokinetics profile does not necessarily mean that such materials could easily be transformed into pharmaceutical agents. The decision to develop a given compound as a product of drug discovery to a commercial dosage form does not depend only on logical scientific criteria. In most real life situations, the decision is based on corporate strategic interests and other commercial concerns that may not be related at all to the scientific/medical merit of the discovered active molecule. Developing countries scientists and institutions interested in entering into biodiversity commercial business or collaboration with the private sector should have some insight on the determinant factors that govern the selection of candidate material for development as a drug.

Another issue which has not been adequately addressed was how to deal with policy considerations at the interface between ownership and access of genetic materials and at the same time addressing the dynamic relationship between valuation and equitable distribution of benefits arising from the commercialization of genetic resources. How should we compensate indigenous communities for the distribution of local knowledge to the development of genetic resources as marketable consumer goods? While establishing benefit sharing schemes it is essential to ensure that traditional systems and cultures are not disrupted by the wholesale importation of concepts and methods from outside, no matter how seemingly benevolent or well intentioned. Local knowledge should be geared to local self-reliance, equitable distribution and access to resources and local capacity and institution building.

A third concern is the establishment of the commercial arrangement that is best suited for the peculiarities of multi-ethnic nations with large populations of indigenous communities and even the special needs of

individual countries. In other words, should developing countries provide access to their genetic materials through research agreements which provide for fixed one-time cash payments (as in the sale of automobiles) or enter into strategic alliances with private and commercial organizations for mutually beneficial programmes for the commercialization of biological resources? What level of value should be added at the source nation before the genetic materials are exported?

Whereas these issues are subjects of constant debate in industrial countries and international seminars and have indeed produced a plethora of interesting and highly informative literature, much progress has not been made in assisting developing countries to articulate workable policy models on bioprospecting. Several examples of on-going bioprospecting projects (such as the U.S. NCI natural products programme, Shaman Pharmaceuticals ethnobotanical based drug development programme, the International Cooperative Biodiversity Group (ICBG) projects, the INBio bioprospecting programme and the integrated biodiversity development projects by BDCP) are now available which make it possible to learn from the experiences of others and to establish better programmes that are specifically designed to meet the needs of particular countries.

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- To identify potential focal points for the UNIDO-ICS network of biodiversity prospecting for industrial promotion and business development.
- To review, assess and collect updated information on projects, methodologies, applied technologies, economic factors for the development of biodiversity prospecting programmes and initiatives.

Profile of Participants

The invited participants were mid-level, senior scientists, institutional and industrial managers working in public or private institutions and / or companies. Some were professionals with experience in industrial exploitation of biodiversity issues (e.g. Taxonomy, inventories of uses, analytical chemistry, biotechnology, business development benefit sharing and intellectual property issues). A quarter of the participants were women.

Profile of Resource Persons

Renowned local and international experts (7 persons) with proven competence on different issues discussed at the Training Workshop were invited to give topical lectures and chair the different sections and discussions. The experts are academicians, R&D researchers and industrial technologists with experience in developing countries in problems related to biodiversity exploitation as indicated in Agenda 21.

II. SUMMARY OF PRESENTATIONS AND REPORTS

Session 1: Introduction to ICS-UNIDO Programme - Presented by Prof. Enrico Feoli

In this session, Prof. Enrico Feoli presented a paper entitled "Overview of ICS-UNIDO Activities and Programmes." The International Centre for Science and High Technology (ICS), is an autonomous institution within the legal framework of the United Nations Industrial Development Organization (UNIDO). Its headquarters are located in Trieste, Italy.

The Centre's mandate relates to the transfer of know-how and technology from developed to developing countries, and is justified by the perception that a competitive industrial and technological capability cannot be built-up without adequate scientific knowledge and without participating in the development and utilization of new and advanced technologies.

ICS's target beneficiaries are identified among scientists, researchers and technologists within industrial R&D institutions, science-based industry clusters and/or industries with their own R&D facilities. Close cooperation with the industrial sector is sought either through direct interaction or through the provision of eco-services by national, regional R&D institutions. To this aim institutional strengthening and capacity building of selected national R&D institutions has been adopted by ICS as a cost effective approach in order to make the required scientific, technical and managerial services available to local industries. The paper outlined the role of ICS in promoting science-based technologies and enhancing industrial development through the establishment of networks.

In the present work programme the ICS activities focus on specific sectors within the areas of chemistry, environment, new materials and high-technology. In selecting the specific subprogrammes and their related activities, special consideration was given to their relevance in relation to the scientific and technological development of developing countries.

ICS operates within UNIDO, an arm of the United Nations. The focus of UNIDO activities is to identify and evaluate sound science and high technologies suitable for sustainably accomplishing its goals. The ICS has established the following mechanisms of operation:

- Training in different forms.
- Serving as a clearing house of information.
- Promotion of co-operation amongst institutions.

The areas of activity of ICS are:

- Earth, environmental and marine resources.
- Pure and applied chemistry.
- High technology and new materials.

The workshop theme, bioprospecting and exploitation of medicinal plants, falls under the earth, environmental and marine science section. However, all three areas work together in order to realize meaningful results.

ICS training activities have been ongoing since 1988. These activities have helped to create a network of people who are willing to work together towards a common goal.

During discussions the issue of dissemination of information on ICS training programmes arose. The idea of a newsletter was discussed but deemed unattractive because most of the time these do not reach the right persons. The network that is now forming is believed to be a more effective means of passing the relevant information.

Session 2: Overview of Global Bioprospecting by Professor Maurice Iwu

It is estimated that over 40% of the world's economy are directly dependent on the utilization of biodiversity (see the report of the Executive Secretary of CBD to the United Nations Special Session on Agenda 21 (E/CN.11/1007/11) 1997. The maintenance of biological diversity has direct impact on global food security, climatic stability, fresh water security and human health. The depletion of plant genetic resources, therefore, threatens the way of life of a large segment of human population and may cause global environmental degradation with possible catastrophic consequences. It is now widely accepted that careful use of these resources can lead to poverty alleviation, improvement in quality of life, improved food security and energy needs, while at the same time creating incentive for the conservation of biological diversity. For individual countries, it has become crucial to safeguard a resource which meets the basic needs of their people without compromising the well-being of future generations and the integrity of the environment. It is the hope that strategies will be identified and developed which will encourage the direction of economic benefits of biodiversity to the people who are in greatest need.

One of the methods advocated for adding value to biodiversity is the development of pharmaceuticals, cosmetics and related products from natural resources. The search for genetic materials with the desired biological activity for development into marketable goods has come to be referred to as biodiversity prospecting or '**bioprospecting**'. Although the term applies to the quest for genetic materials for biochemical investigation, it has become restricted by usage to only commercial activities involving companies in industrialized countries and institutions in developing nations.

Bioprospecting is a very controversial subject and there is hardly any agreement in any aspect of the process among the key players. Much of the controversy has to do with issues of ownership of plant genetic materials, access legislation, and material and intellectual property. In the fore is the problem of deciding on how to value a genetic resources and to agree on what constitutes a fair deal. A major decision in establishing a bioprospecting project is the definition or identification of the overall objective of the program, a realistic estimation of the anticipated benefits and results and a plan for equitable distribution of income generated from biotrade. This has become one of the singular most important pre-requisite for bioprospecting because of the wrong assumption that every north-south realtionship must inevitably be exploitative and the creating unrealistic expectations from bioprospecting.

Benefits arising from genetic should aim to:

I. address the needs of source countries for cheap high quality products and reduce the dependence on imported pharmaceuticals,

II. promote technological development and capacity building,.

III. reward physical and intellectual contributions of individuals and communities who protected, processed and developed the biological resource.

and,

IV. provide incentives for conservation.

The conservation goals must include:

- What are the development objectives to be achieved?

- What are the social and economic forces driving the loss of biodiversity?

- What can be done to reduce or even to reverse the current rate of biodiversity loss?

- What are the priorities within biological conservation?

Prof Iwu identified three major vehicles for the sustainable use of biological resources:

1) Domestic research and development (R&D)

2) Product development through partnership arrangements such as cooperative research and development

agreements (CRADAs) and strategic business alliances (SBAs)

3) Bioprospecting which involves direct trade of genetic resources from developing countries to industrialized nations.

While the latter has received a great deal of attention, the first two have been largely under-utilized. The term bioprospecting has become synonymous with every aspect of exploration of natural resources for industrial production of marketable goods, regardless of whether the activity is domestic R&D or joint collaboration. Key issues in bioprospecting include: access regulation, sustainable sourcing, material processing and benefit sharing. While these issues were clearly recognized by the CBD, successful implementation of the principles enunciated by that conference requires creativity on the part of the stakeholders. A simplicity approach to these issues such as profit sharing, which ignores the distinction between a discovery and the ensuing technology, can be an impediment to progress. Recognition of this distinction is particularly important for lesser-developed nations which may have the infrastructure for discovery but are ill-equipped to develop the associated technologies.

Bioprospecting is affected by both internal factors (availability of material, capacity assessment, material environment, etc.) and external factors (CBD appliance, external markets, partnerships). Examples of bioprospecting projects include the United States National Cancer Institute program, the Shaman Pharmaceutical drug development projects, the ICBG projects in Latin America, Asia and Africa, the IOCD-BDCP initiated bioprospecting project in South Africa based at the Council for Scientific and Industrial Research (Pretoria, South Africa) and the much-publicized biodiversity initiative by INBio in Costa Rica. Each endeavor is unique in many ways and some of them like the INBio model cannot be transplanted to other countries.

BDCP activities in the region include:

1) Training programmes aimed at building relevant capacity in several aspects of bioprospecting.

2) Establishment of ethnobotanical inventories in many parts of Africa.

3) Establishment of the Center for Medicinal and Aromatic Plants at Nsukka, Nigeria, which will perform extractions and bioassays, provide analytical and QA support to the biopharmaceutical and cosmetic industries, maintain reference data of plant extracts and provide training.

4) Establishment of the Fund for Integrated Rural Development and Traditional Medicine (FIRD-TM).

5) Acquisition and maintenance of permanent conservation plots in Nigeria and Cameroon. These plots are being used to create a database for tracking changes in biodiversity, economic value and status of domestic plants facing extinction, e.g. *Prunus africana.*

6) Creation of an interactive database of African medicinal plants which will be linked to other databases on the continent.

7) Assisting institutions and organizations in Africa to establish bioprospecting projects and business developments based on sustainable use of natural products.

8) BDCP is the collaborating partner for the African ICBG which has projects in Nigeria and Cameroon.

BDCP maintains a web site and electronic newsletter. Bioprospecting should focus on resource conservation, material processing and commercialization of the products. For a successful biodiversity project four principal elements must be in place. These are: -

- Sustainabale source of genetic materials,
- Technology platform (capability and capacity assessment)
- Business Development, and

- Equitable distribution of benefits

Professor Iwu was asked to comment on the variability of plant extract composition and the difficulty associated with adoption of suitable reference standards of plant extracts as envisioned in the proposed extract library at the Center for Medicinal and Aromatic Plants. In response, he acknowledged the problems and stated that the initial reference samples would be characterized by chromatographic fingerprinting to accommodate the aforementioned variability. Subsequent efforts would be made to characterize extracts obtained under a variety of conditions. When asked if conservation can be regarded by indigenous populations as a threat to their well-being, Prof. Iwu replied that these populations are receptive to such efforts when alternative sources of income are provided. Finally, in response to a question on capacity assessment, he stated emphatically that there is no single insitution in any of the African countries has the critical mass of scientists that will be required for the successful implementation of biodiversity / bioprospecting ventures, that is from plant identification, through the various process technologies to final product development. He therefore concluded that collaboration among scientists and other stakeholders is essential to the success of the bioprospecting enterprise.

On the operational frame work of BDCP, he explained that the Bioresources Development and Conservation Programme is a non-government and not-for-profit international organization established in 1991 by a resolution at the inaugural meeting of the Steering Committee at the University of Nigeria, Nsukka. The international Programme was, however, formally established in the Earth Conference in Rio (UNCED) at an African forum on Biodiversity Conservation as a network of scientists, industrialists, and policy experts who are interested in the issue of providing a link between conservation of tropical forests and economic development. The main mandate of BDCP is: to encourage the understanding of and encourage the appreciation of tropical ecosystems of forests, coastal marines, woodlands, savannas and drylands as sources of biological resources, which could be used as instrument of sustainable development. To link the well-being of tropical ecosystems with the health of human inhabitants by providing affordable health care for people living in tropical countries through the development of plant based medicines for the treatment of tropical diseases. To assist indigenous communities, private institutions and individuals in tropical countries to enter into biodiversity prospecting business (local, national, and international) that guarantees them good returns for their labour while at the same time protecting forest resources. To seek international support for critically under-funded community based biodiversity conservation project. To promote study and research in the area of biological diversity development and conservation.

In order to efficiently implement its mandate BDCP's programme is organized in different activities: Collection and collation of available information on the uses of African plants, with special reference to indigenous food crops, medicinal and aromatic plants, and industrial crops. Monitoring of selected ecological sensitive zones for biodiversity loss. Conservation of tropical African forests by encouraging basic research on various land use options and on the sustainable utilization of tropical forest plants. Stimulation of public awareness and concern about the vanishing resource base of tropical agriculture, and to support the activities of public interest groups that are working on these issues and foster cooperation and communication between them. Initiation and encouragement of efforts by local communities for the conservation and exploitation of biodiversity resources, for sustainable economic development. Encouragement of the establishment of small-scale agro-industrial and marketing enterprises which seek to empower the poor and the powerless to derive maximum benefits from their inhabitants.

BDCP relies entirely on grants and specific project funding for its activities. Although BDCP was conceptualized as a "not-for-profit" non-governmental institution, the program is designed to generate its funds independent of governments' direct assistance. It is envisaged that eventually most of its activities will be financed from royalties and trust funds.

Topic: Intellectual Property Protection, Ownership and Commercialization of Medicinal and Aromatic Products and Processes

Speaker: Mr. Lucas Sese

The paper highlighted the importance of Intellectual Property Rights (IPR) laws within countries in this era of international trade. It outlined the history of the development of laws and pointed out that each law was prompted by a crisis. The crisis at hand is that of protection of indigenous knowledge. It is hoped that some form of IPR law will soon be developed to solve the issues associated with indigenous knowledge and herbal remedies.

The three forms of property rights are: movable property, immovable property and intellectual property. Intellectual property rights involve the creaction of the human mind. One form of protection under IPR is the patent. Patent laws protect inventions which have been proven to be absolutely novel and indicate possible industrial application. When an applicant of the patent has demonstrated an invention, exclusive rights are then given on condition that the technological information is disclosed to the state in the form of a patent document.

On the issue of biological resources a situational analysis of the North (developed) versus South (underdeveloped) was given. The availability of IPR in the North for the protection of biological resources has resulted in the biotechnology era. The South on the other hand has been weak in IPR but rich in biological resources and indigenous knowledge. There is therefore an urgent need to develop an appropriate IPR regime to protect these resources.

Topic: Need for Sustained Utilization, Development and Commercialization of Medicinal and Aromatic Products and Processes

Speaker: Dr. James Pearce-Biney

This paper addressed the concern that African traditional medicines have not been developed to western pharmaceutical standards. This factor places traditional medicine as a market commodity in a distinct disadvantage. Traditional medicines come from Africa in crude form to be refined into finished products and marketed at high prices. The crude forms of the medicines play an important role in Africa's primary health care systems and are used by the communities because they are cheap, effective and available to the rural population.

Efforts to improve and control use of these medicines have been frustrated by the way it is practiced; that is, the practitioners often operate in isolation and are secretive. In order to improve and preserve the traditional medicines, training programmes should be undertaken on:

- Conservation measures
- Cultivation of species
- Collection methods
- Preparation of the medicines into appropriate dosage forms
- Control of quality
- Packaging of the medicines in a presentable manner
- Appropriate advertising which is not misleading

In an attempt to control the use of traditional medicines, the Ghanian government has enacted some laws dealing with the registration of herbal and homeopathic drugs. Proper public awareness by the government will be necessary to educate the traditional practitioners about their registration.

Topic: Herbal Medicine Practice in Uganda

Speaker: Godwin Sentongo

Mr. Godwin Sentongo is a traditional doctor from Uganda. He gave a short account of his practice

which he operates on a part-time basis. In his practice, he uses plant materials from leaves, stem/ root barks, stems, roots and flowers. These extracts are sometimes formulated into tablets, creams and solutions and natural preservatives are usually added. He started serious practice in 1985 and treats the following conditions:

- color blindness
- eye defects
- cancer
- HIV/AIDS
- skin diseases
- diarrhea
- diabetes
- ulcers

He raised the issue of availability of raw materials and the need for conservation of some of these useful plants which are being destroyed at a very fast rate. He has tried to acquire a plantation where he will cultivate these plants. He stressed the importance of the various stake-holders, including scientists, industrialist and traditional healers to collaborate in order to maximise the benefits from Africas immense genetical and cultural resources.

Session 3: Panel Discussion: Policy Framework for Bioprospecting and IPR

Following a short introduction by Professor Iwu, Mr. Barnes briefly outlined some of the problems associated with formulating/implementing biodiversity policy within the framework of material sovereignty. Since many of the developing nations face similar problems and since a given genetic resource can often be found in more than one country, the adoption of common regional policies for biodiversity is a viable solution. Due to the low level of participation by African nations at international conventions devoted to biodiversity, the OAU should be empowered to articulate the collective view of African nations at such fora since these deliberations often underpins various aspects of economic developement in the continent.

Mr. Lucas Sese suggested that the concept of intellectual property as originally formulated is ill-equipped to handle African biological resource issues because it does not explicitly recognize community interest. Modern laws need to be passed to address the issues raised by the bioresource problem. Differences between the two international conventions on trade should be reconciled, and African states should adopt laws to protect intellectual property and plant breeders' rights.

Mr. Nnadozie cited lack of political will and a harvest mentality as two major factors responsible for the failure of African nations to formulate coherent policies on biodiversity. Empowerment of NGOs would greatly advance implementation of the CBD. Access to bioresources would be aided by the adoption of a common biodiversity policy by African nations. The likelihood of its adoption would be greatly enhanced if such a policy framework were flexible enough to accommodate conditions that are unique to each nation. African nations should be willing to make concessions so as to obtain assistance for developing their biological resources.

At the same time, industrialized nations should be encouraged to channel resources back to the sources of the biological "mine" in order to compensate the keepers of the knowledge and to assure sustainability.

While NGOs may greatly advance the formulation of policy at the international level, they can not replace constituted nationall governments in negotiating treaties or conventions. Though African governments as a whole have been slow in articulating national policies on biodiversity, some among them have acted quickly when they were threatened with loss of a specific resource.

Report of the Workshop proceeding, Session 4-7.

Rapporteurs: Kent Nnadozie and Medhin Zewdu.

Four sessions were held, namely: Computerized Information Systems and Bioprospecting, Sustainable Sourcing of Medicinal and Aromatic plants, Tools of the Trade and Case Studies of Models for the Commercialization of Biodiversity. A total of eleven speakers gave presentations in the above-mentioned areas. A summary of their presentation is as follows:

Topic: Resource Systems in the Use of Medicinal and Aromatic Plants

Speaker: Prof Enrico Feoli.

Two types of database systems exist: resource and exploitation. Resource databases include information on soil, vegetation and atmosphere. Bioprospecting databases include information on chemical screening, pharmacological and clinical tests as well as marketing information. Key elements in promoting the industrial use of medicinal plants are: the interaction of people with the resources, the laws which regulate their use and IPR. Databases are a key factor in medicinal plant use. It is better to form small data bases, e.g. taxonomical data of a plant with synonyms, vernacular names etc., and link these databases together to form a network. The database of Pretoria was cited as an example which was developed by the National Botanical Institute, but which the speaker considered to be too large and cumbersome to be of any practical use. Whenever a pharmaceutical industry is interested in developing a drug from plants, it should have a close relationship with the healers who have the knowledge and operate within a system where all parts of the system will benefit.

Questions raised:

- How can you protect the ownership rights of indigenous knowledge if people put all the information into a database?
- What information source can one rely on for cultivation?
- Can any arrangement be made among the different types of data bases?
- What do you mean by a plant trial?
- The difference between constituent and isolate.

Answers.

It's true that if the information is already put in the database which is accessible to others then there is no way to protect the IPR for that particular information. [It is possible to link one database with another but the task is simplified by having at least one or two simialr data-fields.

Plant trial means bioassay of isolates or even crude extracts. The difference between isolate and constituent is that an isolate can be a single or group of compounds separated from the crude extract, whereas constituents are compounds present in the extract.

Topic: Policy Initiatives on Bioprospecting in Ghana - Ministry of Environment, Science and Technology

Speaker: E. P. D. Barnes.

The speaker briefed us on the objectives and activities of the office, of which policy formulation on the convention of biodiversity is the major one. Development of legislative policies and data management issues are taken care of by the office. Under GEF there is a bioprospecting study going on to manage the country's biological resources. The national biodiversity policies cover various activities involving

conservation and sustainable use of the resources. It is recommended that a biodiversity unit be created as a focal unit to facilitate activities and strengthen and give support to identified research units or regulatory bodies. Ghana is one of the two African countries involved in the UNEP-funded project to study biological resources. In this regard, five local institutions are networked, each with its own database. He outlined other biodiversity projects currently being implemented in Ghana. The country has formulated a policy regarding biodiversity and the establishment of a unit for management but not control of bioprospecting. Participation of the private sector in bioprospecting is emphasized. He stressed the need for a biological inventory and the establishment of a resource database. He elaborated on the usefulnes of a database and cited the PRECIS system in Southern Africa and the CISMAP being developed by BDCP as examples. However, a major disadvantage is that this exposes the information, thereby endangering the IPRs.

Questions Raised.

- In what way is the biodiversity unit to be created?

- Is it going to be a control unit or a management unit which facilitates things to happen smoothly?

- How do the academic institutions help the entrepreneurs in promoting bioprospecting activities?

- How research projects are identified and sources of funding for development were also raised.

Answers.

- The biodiversity unit is a coordinating unit or a committee made up of members from different institutions and the unit is represented by one person as a secretariat office.

- The unit is just a management unit and not a control agency. The issuance of permits and related activities are handled by separate agencies. These two things have been separated.

- The role of academic institutions is in the identification and confirmation of plant species upon request. They also provide training programs with their human and material resources. In this term the relationship between the private and public sector is becoming strong.

- As to development programs, demand-driven research activities are being performed for which revenue is also obtained. The government is taking many of these activities off its hands and the research institutes will function based on the society's need.

Topic: Ex-situ conservation of indigenous African plants Biodiversity

Speaker: A.A. Oteng-Yeboah.

The speaker noted that the term "domestication" is preferred instead of conservation in the case of ex-situ conservation. He raised the question: why do we have to domesticate? The justification is that the wild plants are being lost under the land uses now being practiced: uncontrolled fires and unsustainable harvesting practices threaten the plants. The objective of domestication is to assess the regeneration potential of a species. He gave a list of criteria used to select species for domestication and worked out strategies to fulfill the objectives. Some plant species were cited as examples which are rare and threatened.

Questions.

- What is the major application area of biotechnology in biodiversity?

Answer. Biotechnology is recommended as one method in domestication. Tissue culture can also be used in ex-situ conservation as a multiplication method and also genetic transfer. However, the technology is not available for most developing countries. Additional comment was made on the need of cultivation of plants to use for various purposes, especially rare and endangered plants.

Topic: Bioprospecting and the Conservation of Biological Resources.

Speaker: Nat Quansah

The speaker described bioprospecting as the search for wild species and their products with actual or potential use to humans. These products may be commercial or non-commercial. He described the conservation concept as the management of human use of the biosphere so that it may yield the greatest sustainable use or benefit to current and future generations. He noted that preservation is total embargo, i.e. protection from the local community itself who used to conserve the resources. Bioprospecting is an inventory of economic venture that depends on biological resources and conservation is the management of the resources available. Bioprospecting strategies were discussed as: taking something and putting something back to keep the balance. Bioprospecting has to be carried out within the confines of the principles of conservation.

Comment.

"How much" should be the key question in bioprospecting. This is usually the missing element from most bioprospecting ventures.

Question

- What is the experience of conservation and bioprospecting in Madagascar at the farmers' level?

The answer for this question is that as we prospect we build trust with the people. Upon request from the local community a clinic is built for health care and there the traditional healer and the doctor sit side by side. The patient is diagnosed first by the healer and in case the patient can not get help from the healer, the doctor interferes. Since the community gets such services from the biodiversity venture they help conserve the resources.

Regarding sustainable use of the plant, if for example the root part is used by the healer, the plant might become extinct. For this reason the academicians should help by determining whether the constituents are also found in other parts of the plant (leaves, stem, seed ...). As a consequence the healer will be convinced to use other parts of the plants. In this context post-graduate research is also involved to promote the sustainable use of medicinal plants.

Topic: Information on Gambian Pharmaceutical Service and Regulatory Conditions:

Speaker: Momodou Cham

The speaker gave a general overview on the situation of his country related to pharmaceutical industry regulations and drug control activities. He stated that up to the mid 70's, the country had good forest cover but due to tourism, it has been much decreased. There is an attempt to regenerate the vegetation. Regarding medicinal plants there is no clear-cut policy, but few modern herbalists exist in the country. The role of a regulatory body was also mentioned for the control of efficacy, safety and quality both for the locally manufactured and imported pharmaceuticals. The drug control laboratory within the institution has very limited capacity in giving analytical services. Future plans include formulating a team to work for the better use of traditional medicine. This is mostly done now by individual arrangements and there are constraints such as unavailability of botanists.

Question

- What kind of pharmacognosy training can be done at a university level?

The answer was there is no university in Gambia and people used to get trained overseas.

Comment:

The professionals should have the courage to face the governmental officials as to formulating a law for the protection of the forest. As to the certificate for the items imported from abroad, the regulatory body used to be consulted for quality by the customs office. The point that herbalists import materials brings up the issue that there is a lot of cross-border movement of herbs and medicinal plants and therefore

international co-operation is required.

Topic: BDCP Program in Guinea

Speaker: Barry Foula

Foula informed the audience how the BDCP was established in Guinea. It was started in 1994 with the help of Prof. Maurice Iwu. Goals of the program were: production of low-cost medicine, inventory of medicinal plants, rural community assistance for better use of flora, etc. Data collection of potential medicinal plants was conducted with scientists from Shaman Pharmaceuticals. With respect to IPR and the Shaman reciprocity program in Guinea, there was not much worry about. The major interest was just to start and assist the traditional healers groups. In-field compensation was started from 1996-97 with the BDCP- Guinea to the National Association of Traditional Healers. They gave information as to what plants to look for and where to find them.

Question:

- How do you believe that the companies keep the agreements?

The answer was that both partners should have to respect norms and if it is so, there is no problem. The company has a set of criteria for sharing benefits but there is emphasis on the need to develop social links and trust which go beyond just financial returns.

Ethnobotanical Collection and Tracking Methods for Medicinal Plants Research by Julie Chinnock

Ms. Chinnock's paper described the step-by-step process involved in carrying out bioprospecting activities and highlighted her personal experiences in botanical collections in Guinea, which is part of the program by Shaman Pharmaceuticals for the expansion of ethnobotanical and ethnomedical drug discovery in the tropics. The program involves a combination of traditional and modern scientific knowledge and procedure in local and global health care efforts. The importance of in-country scientists in the entire set-up is recognized. Legal and appropriate procedures such as obtaining all necessary permits must be adopted before carrying out the venture, as well as being practically prepared by using the appropriate tools and equipment for the collection, identification, cataloguing, preservation and storage of plant samples. One of the primary steps that should be taken before commencing any field work is that of "dereplication": assessing what work has been previously done so as to concentrate efforts and direct resources towards new candidates for collection and testing. During the question and answer period, when asked whether there are alternative local materials for constructing plant presses, she indicated that there are many different options. The important thing is to arrive at the desired conditions and results.

Mr. Feoli observed that this is an example of a company to learn from which has gone into the practical activities of bioprospecting. He went on to ask if there were any initial agreements, especially at the national level, to regulate their activities referring especially to IPR issues. Prof. Iwu in response stated that although no national laws currently exist covering biodiversity companies, Shaman and the BDCP try to work within existing laws to make sure that none of these are being contravened.

Ms. Chinnock added, however, that apart from obtaining permits both at national, regional and local levels, elaborate agreements may be entered into for the purpose of regulating their activities as well as stipulating other conditions such as scope and compensation issues.

Topic: Herbal Medicine: HIV Therapy in Uganda

Speaker: Bwogi Kanyerezi

Prof. Kanyerezi gave a survey of some of the cases handled by him involving the treatment of HIV patients with herbal preparations. According to him, he had been approached by herbalists who claimed that they had remedies for HIV infection. His approach, in order to maintain the confidence of the herbalist, was not to investigate the type or source of their herbs but basically to find out if their claims were authentic. After collecting the substances presented to him, he subjected them to series of tests

before administration. These tests include determining whether they had anti-viral activity, toxicity and their therapeutic indices- the higher the index the better they are as drugs. He said that no single drug is used since the patient will develop immunity to it within a few months, so a cocktail usually of 4 or 5 different types is used to ensure continual effectiveness.

Having established the substance as a potential drug, he went on to conduct clinical trials over a long period with varying results ranging from excellent to well to poorly. In one of the six cases presented, one of the patients was found to be completely negative of HIV after the course of treatment even up to one year afterwards, while one died in the course of treatment and other varied in between these using their "CD_4 count." Asked whether it cannot be said that he has found the cure for AIDS, he refused to make a categorical claim to that, stating that a lot of other factors could have contributed to the "curing" of the one single patient out of several, but trials are still going on.

Returning Benefits from Ethnobotanical Drug Discovery To Native Communities by Katy Moran

The paper was also based on a case study and practical experiences in bioprospecting with particular reference to compensation issues. She gave a brief background of the Healing Forest Conservancy (HFC), which is a charitable organization established by Shaman Pharmaceuticals in 1990 which channels back benefits to local communities in which bioprospecting activities had been carried out as well as to the government.

Article 8(J) of the Convention on Biological Diversity is the basis for the initiative although its construction is weak in compelling corporations to channel back benefits and in making sure that the benefits when provided will actually reach the local communities for whom they are intended. This led the HFC to establish their own goals of communal compensation which include: the promotion of sustainable development, generation of local employment, provision of resources to survey, demarcation and deeding of historic territories to indigenous groups, development of local markets for non-timber forest products such as medicinal plants and strengthening indigenous institutions.

To these ends they established certain long-term compensation principles which are that:

1) There are two processes for compensation; one for the government for the use of biotic resources and the other for indigenous groups for the use of cultural resources.

2) That all involved will share equally, i.e., a percentage of Shaman profits will be distributed to all the indigenous committees and countries with which it has worked regardless of where the actual plant sample or traditional knowledge originated.

3) That the process should benefit community groups as a whole and not individuals.

4) Long-term compensation persists as long as Shaman shows profit. And there is deliberate effort not to give too much too soon, since it is better to give small amounts over a long period of time than to give huge single amount that will either overwhelm the locals' ability to manage it or create other problems.

Based on these, the HFC has created a mechanism to deliver long-term funding to finance programs in a consistent manner, offering flexibility in responding to local needs and in using locally-elected boards to manage funds. The mechanism is the establishment of trust funds whose boards are selected democratically, serve for a specified term and have fiscal responsibility for funds. The boards do not implement projects, but will decide which ones to fund.

A pilot Trust Fund is already being established in Nigeria in collaboration with the BDCP to which an initial sum of $40,000 will be provided.

During the question and answer session, Mr. Dave Stephenson observed that the advantages of this sort of mechanism is two-fold: first, it spreads the risk - decreases the risk of each of the indigenous groups in negotiating and getting benefits, and secondly, it provides a credible vehicle for recycling benefits.

Topic: Medicinal Plant for Industrial Exploitation

Speaker: Deborah Kioy

Ms. Kioy presented the situation in Kenya, where medicinal plants are extensively used in traditional medicine and most conventional pharmaceuticals originate from plants. She gave an overview of exploitation strategies and the inter-relationships inherent and necessary for the successful commercial exploitation of medicinal plants. The activities of her department are restricted by economic limitations, particularly in the inability to travel and consult directly as well as the lack of necessary equipment for thorough analysis and tests. Within those limits, they have been able to do extensive work with traditional medical practitioners and also establish a herbal garden. It was observed during the discussion period that whatever methods and approaches that are adopted, it is paramount that good clinical practice is observed, as this would assure consistency as well as reinforce credibility.

Topic: State of Bioprospecting in Mali

Speaker: Flabou Bougoudogo

He presented a paper on behalf of Prof. Arona Keita. The paper highlighted work so far done by Prof. Keita in making several commercial herbal preparations, despite limited resources. He has collaborated extensively with local herbalists and also has many other aromatic plants currently under study. He uses the outcome approach, working closely with clinicians.

Workshop Day Three, 24 September 1997.

Summary of the Major Topics Discussed.

There is an increasing interest of industries in United States, western Europe and other northern countries in the biodiversity of the South. This trend is likely to continue for at least the next three years, potentially meaning major economic benefits for the South. But in order for the owners of these resources to benefit, certain laws and regulations must be developed.

Botanicals are not regarded as medicines in the U.S., but as dietary supplements. The quality and safety of the botanicals are critical for export to the U.S. Botanical monographs are being developed by the U.S. Pharmacopoeia (USP), but public standards are only meaningful if enforced. Good cultivation practice and good harvesting practice are critical for quality assurance of botanicals. After quality control of the botanical, the next step is the formulation of the material into a suitable dosage form. Further research into phytomedicines could have major benefits, and the important role of the traditional healer cannot be overemphasized.

Comments: On David Stephanson's talk Topic I.

Katy Moran: Importance of getting involved in national laws as citizens of those countries.

Edwin (Ghana): We are being instructed by the western world - told legally what to do. It seems the contracting party is the U.S. and decisions are being made by the west.

Alfred Oteng (Ghana): Who is going to receive compensation is a big problem.

Topic: Key Legal and Ethnoecological Components of a Bioprospecting Agenda

Speaker: David Stephenson

1. Ethnobotany, Bioprospecting, Intellectual Property Rights.

Various definitions of the above subjects were proposed - some accepted, some not.

Legal and ethno-ecological ramifications must be considered.

Indications are that there is an increasing interest of industries in the U.S., western Europe and other Northern countries in biodiversity of the South. This trend is likely to continue for at least the next three years. It is believed that Southern countries have a lot to benefit from this project.

Cultural differences must be understood. It must be understood that many people are dependent on the biodiversity, including the indigenous people. Indigenous peoples is another term with many definitions. Biodiversity is the source of 99% of the world genes. There is an important link between biodiversity and cultural diversity. These important cultural wealth and values can be lost among scientific and industrial objectives.

Local Communities.

Local communities must have a right to;

a) Control their resources.

b) Compensation from the use of their resources.

c) Their knowledge.

To bioprospect, we need to be aware of ;

1. IPR
   - Western legal term.
   - Different kinds of instruments developed.
2. Licensing agreements.
   - These should be ongoing, perpetual relationships.
3. Various multilateral conventions, e.g. the CBD.
4. Natural laws.
5. Ethical guidelines.

Declaration of Belem.

1) Many people are dependent on tropical rainforests that are disappearing.

2) 99% of the world's genetic resources are maintained by native peoples.

3) There is a distinctive link between biological and biocultural diversity.

A number of these concepts have been developed in the last 10 years. Biotechnology is in the fastest growth phase ever. All countries should be poised to participate.

Parties to the bioprospecting venture must come to agreement on:

- Sharing of the resources, e.g. financial gains.
- Proper compensation of the stakeholders.

Legal and ethnobotanical frameworks need development. IPR is a western legal term. It connotes private property by one person. TRR is better suited.

Useful comments on the topic.

1. Ratifying a convention is not the same as implementation. National legislation should be developed to incorporate the convention.

2. Definition of indigenous people.

This phrase is not useful for Africa. No African groups have been identified as not being indigenous. Therefore, the beneficiaries are the local people or government.

3. Firm legal structure needs to be implemented :- Conventions, treaties, laws contracts, agreements, ethical guidelines.

4. CBD- article 8(j) is important even though it can be overwritten by other laws. Local peoples are parties to the agreement.

Topic: Role of Botanical Products in the Health Care System and Scientific Issues in the Development and Establishment of Public Standards for Botanicals

Speaker: V. Srini Srinivasan

Botanical Standardization

Herbal preparations have a place in the health care of both developed and developing countries. There is an increase in botanical use in the U.S., up to 20% annually. Botanicals are not regarded as medicines in the U.S., but as dietary supplements. 1/3 of Americans use alternative health care. 80% of Africans use botanicals. The quality and safety aspects of botanicals is of concern. Some chemical and pharmacological trials are carried out. The Office for Alternative Medicine and the FDA are working together to develop standards.

Criteria Used by the Subcommittee to Identify and Prioritize the Botanical List:

1. Some evidence of beneficial pharmacological action and a history of use in traditional medicine.
2. Absence of a significant safety risk
3. Interest by a regulatory agency (if present, e.g. FDA).
4. Characteristics typical of a USP monograph.
5. Extent of use.

Botanical Monographs

Major Limitations:

- availability of reference standards

- pharmacognostic identification (positive I.D.)

Components of the monographs

1. Description of the botanical
2. Packaging and storage
3. Appropriate labeling (expiration date)
4. Latin botanical name
5. Identification - pharmacognostic
6. Marker substance - positive identification
7. Other substances (contamination test)
8. Foreign organic matter
9. Microbial contamination - bioburden load
   - This is dependent on the end use of the botanical
   - Aflatoxin content
10. Pesticide limit
11. "Content of ingredients" rather than "active ingredient"

For good standard botanicals to be obtained, good cultivation practice and good harvesting practices should be observed.

Comments Momodou Cham (Gambia)

1. Reference substances for botanical in other countries

USP has developed a number of reference standards - other countries have their own pharmacopeia.

2. Technology Transfer Nat Quansah (Madagascar)

It was observed that a useful contribution of USP could be the training of scientists in the South in the development of reference substances, since a number of plants in the South are not even known in thr U.S.

Topic: Pharmacognostical Standards For Crude Drug

Speaker: Prof. Tony Elujoba

Identification And Quality Assurance.

Stressed the need for standardization.

Practical steps for setting pharmacognostic standards:

1. Authentic confirmed identity.

   Binomial System (Genus, Species, Authority, Variety, family)

2. Macro- morphology of fresh drugs, leaf, fruit, flower.
3. Histology / microscopy of fresh powered drugs.

   Qualitative: surface t.s.

Quantitative: micrometry, etc.

4. Structural standardization.

   Limit of adulterants.

5. Analytical standardization.

   Qualitative - alkaloids, etc.

   Quantitative - total alkaloid content, etc.

6. Physical constraints.

   Spectroscopic.

There are sometimes problems with species confusion. We should increase the activity of standardization with toxicity studies. Consolidation of science findings, formulation of production research and registration.

Comments

Nat Quansah (Madagascar):

Disagreed with the often repeated allegation of mis-identification of species by healers. Species may be told apart by the healer by their own science and species may have their own properties even if they cannot be told apart in a laboratory.

Response: no-one is perfect.

Traditional Healer (Nigeria): God has given traditional healers the knowledge and ability to heal. The inner spirit is the science. Different parts and species can be used and still be active.

Stella Inya-Agha (Nigeria): Different parts may be used for different therapeutic areas.

Topic: Process Technology for Production of Phytopharma Medicines

Speaker: Prof. R. Nasipuri / Kunle O.O.

Definition of herbal medicines (WHO)

- Definition does not include isolated compounds.

Processes

1. Extraction
2. Concentrating and drying
3. Formulation of product

Extraction

- Size reduction
- Solvent extraction
- Process selection

Concentrating / Drying

- Evaporation at atmospheric pressure

- Vacuum evaporation
- Freeze drying at times

Product Formulation

Pre-formulation studies

Dosage form selection

Selection of adjuvant

Topic: Ethnobotany and Economic Evaluation of Plant Species in Bafut, Sabga and Oku (NWP of Cameroon)

Speaker: Dr. Clare Wirmum

NWP Cameroon.

- Geography
- Demography
- Administration

Bafut - Vegetation - Savannah to forest.

Forests serve as a useful source of food.

Sarga - Fulani - Area for ethnoveterinary products.

Oku - Forest region (mountain forest)

Cultural and religious value

Area of unique biodiversity

General Vegetation

Forest is of economical value.

Each study area was tackled separately.

The project involved: villagers and local administrators, data collection, educating youths of the area, distributing information according to their villages of origin.

As a policy - Women should outnumber men among the population interviewed.

Information on the dietary value, medicinal value, etc.

Topic: Pharmacological and Clinical Issues Related to Commercialization of Phytomedicines

Speaker: Prof P. I. Akubue.

1. Screening of substances.
   - Blood
   - Non-blood

2. Pharmacological studies on animals.

- Isolated tissue
- Whole animals
- Cell culture

a) Preliminary studies.

b) Detailed pharmacological studies - many pharmacological workers in Africa tend to end their studies at this point.

3. Toxicology studies.

- Acute
- Sub-acute
- Chronic

Specialized toxicity tests.

- teratogenicity
- Effect on reproduction
- Mutagenicity.
- Carcinogenicity

Formulative studies.

4. Clinical trials

Phase I

Phase II

Phase III -multi-centers

Phase IV - post-marketing surveillance

<u>Summary</u>

1 in 1000 tested substances reach clinical trial.

1 in 100 clinical tested reach phase IV.

Time - 7-10 years

Cost - US $ > 10 M

What do we do?

Herbal Medicines in use.

a) Clinical studies

b) Therapeutic studies - Orthodox

- Monitor in use.
  - Clinical pharmacology
  - Therapy
  - Toxic / Side effects
    - Formulation
    - Market

Comments.

Use of plants for simple ailments may not pose a major problem for regulation. However, the regulatory organizations will become more concerned when a phytomedicine is suggested as remedy for a more complicated health problem, e.g. snake bite.

Topic: Phytomedicine Research - Central and Eastern Nigeria

Speaker: F. Okwuasaba

Traditional medicine practitioners are secretive, how do we reach them?

- Importance of the traditional healer in the health delivery system.
- Confidence of the healer in the researcher(s).
- Method of data collection.
- Approach methods.

Multi-disciplinary research at the university level.

- involvement of the clinician
- phytochemistry

Interest areas.

- Fertility and antifertility drugs
- Anti-asthmatic
- Antifungal

Topic: National Agency for Science and Engineering Infrastructure (NASENI)

Speaker: R. Boroffice

Comments

The people know what is good for them - let us reinforce their efforts. Let the government of Nigeria take the lead in supporting the formulation of phytomedicines which have been found to be useful in the country.

Government (through NASENI) has already put in something in process. Efforts are going towards developing what has been started.

Session 11

Technology Management

Chairman: Mr. Piergiorgio Stipa

Rapporteurs: Ms. Patricia Johnson and Dr. Nat Quansah

The program was divided into 4 main parts:

1) Technology Management I.
2) Technology Management II.
3) Panel (group) discussions.
4) Contributed papers by workshop participants.

Each of these parts, with the exception of the panel, followed the pattern of a key presentation after which came discussion, question and comments. After panel (group) discussions, each group reported the outcome of its discussion to the rest of the groups.

Mr. Piergiorgio Stipa showed the existing relationship between ICS and UNIDO and the different arms of their networking systems, mentioned earlier in these proceedings.

He highlighted the Technology Management unit, its objectives and the module strategy.

Prof Maurice Iwu is the link in Nigeria.

The main strategies for the Enugu workshop are:

a) The market requirements and trends in the African natural product industries, to be taken up by Dr. Nigel Gericke.

b) Strategic business alliance and international cooperation, to be taken by Prof. Maurice Iwu.

Topic: Technology Management I

Speaker: Dr. Nigel Gericke, South Africa.

The above topic was introduced under the following headings: Mission, Focus, Business Plan,

Regulatory Environment, Virtual Organization, Joint Ventures, and Raw Materials. The mission is to make safe, effective phytomedicines for our individual countries, whereas the focus would be on phytomedicines only (not on phytomedicines, cosmetics, nutraceuticals, etc.) With the focus and budget in mind a business plan can be developed. The regulatory environment in the country should be understood. The virtual organizations must be linked. For example, universities and market sources should be linked with other institutes. Joint ventures address a large market and thus overseas partnership is required. Accessing the global market increases technology transfer and provides capital. The raw materials should be in large supply, cultivated sustainably.

Two case studies are Rwanda and South Africa.

a) Rwanda - They used to have a well developed phytomedicine program but it has been devastated by war. They cultivated the plants and even produced their own ethanol.

b) South Africa - The annual sales of medicinal plants is about $ 12 million, made from about 500 species. 20-50 species are on the endangered list. Traditional medicine is a complete unit, all of which we may not understand "scientifically". The working of the phytomedicine production and market in South Africa was described. Four of Dr. Gericke's own products were shown - "Healers' Choice" for various ailments using home remedies.

Topic: Technology Management II

Speaker: Prof. Maurice Iwu (BDCP).

He started off with a transparency of a circle divided into quadrants containing the following: Sourcing Issue, (biodiversity, culture, collection and ethnobotany); Technological Platform (extraction, production and storage facilities); Project Management (sole effort, network alliance and sub-contracts) and Commercial Development (marketing concerns, IPR).

A strategic business alliance between two bodies depends on whether there is a network or some form of cooperation in place. Analyzing the basic elements of strategy using the BDCP herbal product plan as an example, he outlined the major questions - What? Who? and How?

What herbal products is BDCP interested in ? Whole herbs, standardized extracts, phytomedicine, and formulation. Who is involved? A wholly owned subsidiary. How will this be done? The establishment of a local base, or partnership or strategic business alliance.

The capability of each party should always be determined and in research collaborations a relationship rather than a deal should be established. The principles of successful partnerships are finding a partner, creating a contract and managing the partnership. The latter is one of the greatest problems as frequent communication is desired, and this sadly is a major flaw in Africa. He said for each arrangement a focus is essential whether for phytomedicines or phytonutraceuticals and health foods.

Most Africans seem to settle for handouts rather than benefits from the bioprospecting trade. Bioprospecting should involve the local communities. Both parties should work on a partnership that enhances both groups rather than settling for selling extracts, which would only bring in pennies now and deny one from all the benefits in the future.

Topic: Case Study "Le CABAS" Center for Research and Production of Phytomedicines and Cosmetics - Yaounde, Cameroon.

Speaker: Dr. Rose Abondo.

The objectives and perspective for setting up Le CABAS were outlined. Its main focus is on dermatology, as this is a common problem among African women. Using the African pharmacopeia, she was able to formulate several products and phyto-cosmetics including: scarring oil, medicinal soaps and oils, regenerating soaps, and oil and masking cream. The commercial circuit for such products should be functional at both national and international levels.

Questions and **Comments** for Session 11.

BUSINESS DEVELOPMENT I - **Dr. Nigel Gericke.**

Q. From Dr. Foula Barry.

What is the cooperation like between South Africa and other countries or institutions concerning traditional medicine?

A. It is informal, though some external groups are already approaching South Africa with funds. Therefore linkage is based on personal contracts.

Q. From Dr. Stephenson

How is the whole traditional, cultural context protected and properly compensated for by this marketing model?

A. A book entitled "Medicinal Plants of South Africa" has been written to increase the awareness of the public on its rich reserves. There is also a great deal of collaborating between traditional healers and scientists and more companies are getting involved. A trust fund has also been set up. Some of the proceeds of any phytomedicine sold is put in this fund.

From Prof. Feoli

Your presentation goes directly to the point and aim of this workshop, in view of industrial development and production. I would like to stress the importance of finding a focus among many alternatives. This requires the analysis of the market, especially the local market, and careful analysis of the resource system from which raw materials will be provided. A clear and careful plan involving the technology needed will facilitate the intervention of investors.

Q. From Mr. Cham

What information needs to be provided on the package to satisfy regulatory authorities in a foreign country? Also, what is the role of the regulatory authorities in South Africa in registration, etc.?

A. There is a consumer information leaflet accompanying each phytomedicine, which is in the vernacular language and includes a warning that it must not be administered to pregnant women, children under twelve and lactating mothers. It also includes the storage conditions, constituents and dosage.

A. The regulatory environment is a nightmare in South Africa; there are no laid down procedures.

Q. From Prof. James Pearce Biney

Traditional healers or herbal practitioners fall under many groupings, namely: herbalists,

spiritualists, mystics, etc. It appears that in South Africa regulatory mechanisms concerning phytomedicines are progressing. May I know if regulatory mechanisms carry the practitioners (i.e., bring them under one umbrella, improving their preparations, packaging, etc)?

A. There are about 200 different groups of traditional healers but they are working together to form a National Association. Until that is done very little influences their practice.

Q. From Dr. Angela Duncan

You used the marketing term "World Class" when referring to your extracts. Could you elaborate on what you mean by that measure and standard?

A. The standards used are mainly those of Germany's, which owns 50% of the world's extracts. However, for standardization, specific strains are used for the phytomedicine preparation for (the brand name we call) "Healer's Choice."

Q. From Dr. Stella Inya-Agha

Considering that affordability is a key factor in phytomedicinal production preventing the completion of products, what are the ways you exhibit cost-consciousness in product development and packaging?

A. The "Healer's Choice" is cheaper than most phytomedicines or drugs on the market, though a detailed market survey has not been done.

Q. From Prof. Akubue

Are there some traditional healers who produce their preparations and have them sold in the market or shops? If there are, do the regulatory authorities allow such sales and if they do; why the objection to the marketing of your products?

A. The regulatory authorities do not bother the small-time traditional herbalist working in his small village but if he gets too successful they clamp down on him.

Q. From Mr. Barnes

Is there any programme which allows for the introduction of quality and consistency into the operations of traditional healers /practitioners in South Africa?

A. There is a lot of fighting between the healers; therefore, no-one can get involved.

Q. From Dr. Efange

What is the capital market like in South Africa?

A. Not well developed and certainly not like the United States. The capital base for a phytomedical industry does not have to be big. One can start off small; such a case would not need a joint venture.

Q. From Dr. Lisa Meserole

a) When you make a phytomedicine, traditionally one uses a decoction or infusion, and produces a tincture (fresh or dry). How do you know what the difference in therapeutic effect is and how do you estimate shelf-life? b) What was your strategy for introducing these new phytomedicinal

products into the market?

A. All the constituents of the four different products of 'Healers' Choice' have been used as tinctures for 4,000 years, so one was actually going from known to unknown and checking the therapeutic effects, but stability tests and shelf life do constitute a problem.

A. The main strategy for introducing the new product was first reconfirming the plants' traditional use by other healers from different parts of the country.

Q. How does the regulation on phytomedicine compare with the regulation on conventional drugs?

A. As long as the plants have had a long traditional and safe use, it is considered as a phytomedicine, therefore only some countries would insist on clinical trials; whereas this is a must for conventional drugs.

Q. From Mr. Lucas Sese

Are brand names for phytomedicines registrable in South Africa as trade names?

A. Some are and others are not, but they could be registered under phytomedicines.

Comment From Prof. Iwu

The regulatory environment was thoroughly documented in the proceedings of the last workshop on phytomedicines. The existing situation in South Africa is different from that anywhere else in the world because multi-shops which have the African-Indian influence sell herbs as well as phytomedicines.

Questions on Technology Management II - **Prof. Maurice Iwu.**

Q. From Dr. (Tr.) Ossuji Nwaenyi.

Is the door of BDCP still open for admission of new members? If so, can one apply through Prof. Iwu?

A. No membership is required for participation in BDCP activities in Nigeria but in Cameroon BDCP is a membership organization which makes it appear closed. Participation is mainly by individuals but the benefits are aimed at communities rather than individuals.

Q. From Dr. Nigel Gericke

Is there any synergism between new drug discovery and phytomedicines?

A. This is being worked on.

Q. Dr. (Mrs.) Claire Wirmum

Since the concept of traditional medicine and its relationship to modern medicine is complicated and secretive to the scientist, could BDCP not open a school of herbal medicine in any African country to break down these barriers?

A. BDCP does not have the resource base to handle that. OAU should look into such an establishment. However, the people at 9th mile have already arranged themselves in a "School". The schools of pharmacy have also introduced Herbal Medicines in their curriculum.

Q. From Prof. Oteng Yeboah

What can be done to freelance collectors, since they cause so many problems, especially in benefit sharing?

A. Nothing can be done, but countries should work on setting up the right infrastructure so that they do not lose out on potential bioprospecting.

Comment From Dr. Nat Quansah

Catharanthus roseus was picked from the database but it was indicated for diabetes, so the information was known to the whole world.

Le CABAS Case Study - **Mrs. Rose Abondo**

Q. From Mr. Barnes

What programmes have been instituted to ensure the sustainability of the raw material base?

A. Some are used as food and are thus cultivated for such. However, there are plans to cultivate more in the future.

Q. From Mr. Aliyu Bindawa

Have you made any efforts to test the side effects of your products?

A. Most are essential oils so they are safe, and they were tested on my kids.

GROUP DISCUSSION

Three discussion panels were selected, covering three areas:

A. Policy considerations, access, IPR and benefit sharing.

B. Conservation and sustainable sourcing.

C. Biotrade and phytomedicine.

The issues were doscussed and appropriate solutions recommended within the context of the theme of the workshop. Group reports were presented to all participants for comments. Below is the outcome of the various group discussions.

GROUP A

SUBJECT: Policy Considerations, Access, IPR, and Benefit Sharing.

CHAIRPERSONS: Dr. Sese and Dr. Stephenson.

RAPPORTEUR: Dr. (Mrs.) Abondo.

The panel agreed that:

- National legislation is a key issue for the application of the Biological Convention.

- There is a need for participation of everybody (scientists, universities, industries, and local communities.)

- This participation includes benefit sharing and intellectual property rights.

- It is important to assure the promotion and also the inventory of endangered species.

- There is a need to regulate and enforce regulations for bioprospecting (CBD).

- The access and the ownership of knowledge and resources must be controlled.

- There is a need for multilabel harmonization (national and international).

Group B

SUBJECT: Conservation and Sustainable Sourcing.

CHAIRPERSONS: Dr. Nat Quansah and N.C. Obialor.

RAPPORTEUR: Dr. M. K. Cham.

How do we get material?

What do we want to source?

Sustainability?

What is the material?

Where is it?

How available is it?

Identify and make an inventory of what is available.

Source of information for the inventory?

- Traditional healers.
- Institutions - universities, colleges, forestry etc., herbaria, NGO's.
- Farmers and other members of the community
- Traders in herbs.

Inventory

- quantity and distribution.

Lots of questions need to be asked before starting the project.

Knowing what we want. - FOCUSING

Dangers to the Plants.

- Traditional practices, e.g. farming habits.
- Traditional use of the plant.
- Harvesting methods.
- Cultural beliefs, e.g., hunting.
- Land use and land use change.
- Land tenure.
- Limited assessment of the impact on the environment of some of the development activities.
- Bush fires.

1. Changes in the farming practices - introduction of technology.

2. Training and Policy

   - Harvesting techniques.

3. For sustainability, the ownership issue needs to be solved.

4. Environment impact assessment.

   - Impact on all of the vegetation needs to be put into perspective.
   - It should be an on-going activity/process.
   - Have in place a good environmental planning programme.

5. Effective monitoring of the conservation programme; this complements the training.

6. Review and develop the laws. In the process of developing these laws, the local communities' participation is critical.

7. Enforcing the conservation laws.

8. Resources to implement the conservation programme should be available.

   - Human and material.

9. Domestication and cultivation both *in-situ* and *ex-situ*.

10. Conservation measures should be put in place at the very beginning of the bioprospecting project - individuals, companies, institutions.

11. Need to take into account the gender situation and especially the role of women in conservation.

GROUP C

Biotrade and Phytomedicines- key issues and solutions.

For the purpose of the discussion we are restricting the workshop to issues relating to the plants in local and international trade, from a particular country.

Inventory.

There has to be an inventory of the species in the trade, the quantities of material traded, the ecological status and financial value. This information should be databased. It is recommended that the database be maintained by an independent group because of the inter-dependent nature of the information. Access and control must be addressed. Funding would need to be obtained for the inventory and database.

Identification and quality.

A facility, preferably university-based, would need to be established to identify plant material in the trade, and higher quality standards should be made appropriate to the level of product - raw material through to finished product. Quality assurance should be part of any product development.

The market.

The existing markets need to be identified and quantified and the needs of these markets should be addressed. New markets need to be identified.

Stakeholders.

The needs of all stakeholders need to be identified and addressed.

Points Made.

- Inventory and database of all information.
- Site, control, access, and funding for the inventory and databases.
- Methods of identification necessary.
- Standards set.
- Country-of-origin testing vs. receiving-country testing.
- Differentiate between indigenous and exotic plants.
- What species are threatened and which are at risk or endangered in the trade.
- Sources of funding for research and for propagation.
- Who are the stakeholders.
- What are their needs.
- Storage conditions.

- Conservation and sourcing - including indigenous knowledge.
- Transportation.
- Packaging.
- Differentiate between the intended uses of the product - foods vs. medicine, and for medicines, self-care vs. prescription.
- Identify market needs, identify future markets.
- Differentiate between wild-harvested and propagated.
- Identify the skills and knowledge of the stakeholders.
- The distribution chain.
- Management and control from harvest to consumer.
- What are the needs of the stakeholders, including IPR.
- What are the effects of the trade on the ecosystem.
- What are the effects of GATT.
- Identification of raw materials.
- What is the socio-economic impact.
- Flexible control of the supply to prevent prices crashing.
- Indigenous knowledge.

Topic: Research and Development Activities on Medicinal and Aromatic Plants in Ethiopia.

Speaker: Dr. Medhin Zewdu.

The speaker gave an overview of R&D activities of medicinal plants in Ethiopia. The national body is the Science and Technology Commission, under whose umbrella are four councils - Industrial, Health, Energy, Mines and Environment and Agricultural. Each is given a mandate on a specific aspect of the country's development programs. The institutions involved in R&D are: the Chemistry Department of Addis Ababa University, Essential Oil Research Center of Ministry of Industry, Drug Research Development of Ministry of Health, Pharmacy school of Addis Ababa University, Biodiversity Institute and Pathobiology Institute) The activities of the Essential Oil Research Center (EORC) and the Biodiversity Institute were outlined.

Traditional medicine is well recognized in the health policy of the country. EORC has 3 essential oils (lemon grass, *Palmarosa*, and *Citriodora*) and 2 spices (*Capsicum* and ginger) have been developed. Extraction industries are in place. The Biodiversity Institute was set up in 1976 as PGRC/E with the objectives of collection, evaluation and conservation of biodiversity. There has been *ex-situ* collection of 56,000 accessions of about 101 species, including wheat, barley and maize. PGRC/E became the Biodiversity Institute when sustainable use of biological resources was incorporated in its mandate.

Two main programs are going on under GEF and CBDC to make *in-situ* conservation of land races. Other activities of the Biodiversity Institute include a nutrient laboratory and medicinal plant activities. The Traditional Healers' Association (THA) has links with the Biodiversity Institute, which provides office, land and other facilities to the THA. Joint research programs are undertaken with other institutions such as the drug research department of the Pharmacy school, Herbaria and the Chemistry Department. The THA is not involved in this joint research program. A program is being initiated by the

Biodiversity Institute with the World Bank for a medicinal plant inventory and assessment for the phytomedicine industry in Ethiopia.

The main constraints are: difficulty in access to information; lack of collaboration between research institutions and scientists and poor linkages between scientists and traditional healers. The presentation was terminated with 3 recommendations: a need for transparency; strengthening of linkages among institutions and having multidisciplinary teams as well as a proper database for networking.

Topic: Remote Sensing and Application to Bioprospecting in Nigeria

Speaker: Aka Kyrian

Explanation of remote sensing (RS) was given. Activities that negatively affect biodiversity include: heavy infra-structural development; bush burning, farming practices, erosion, deforestation, industrial pollution and increasing urbanization. Information gathering requires field surveys. Traditional or earlier methods (2-method approach) has discrepancies but remote sensing offers a 3-method approach (adding to the traditional approach). Ground-trotting after obtaining images. Remote sensing can be used to determine the manner and type of deforestation. RS is useful for monitoring vegetation information - deforestation, distribution, type, etc., which is valuable for management decisions.

Question from J. L. C. Ibuzo

- What is the cost of Remote Sensing?

Answer: Cost is dependent on what is obtained from satellite owners.

Comments: Prof. Feoli : If one starts from scratch then it would be very expensive. However, if there are facilities already present in a country, RS costs would be low. In any case, RS is the cheapest way of obtaining information with a high degree of accuracy.

Prof. Iwu : If the general environment is not conducive to acquiring and using facilities such as Remote Sensing, then it will be impossible, e.g., no funds to acquire images, no computers to effect good resolutions of images, etc.

Topic: Regulatory Bodies in Cameroon

Speaker: Andre Tchukangoua

Ministry of Commerce - investment code.

MAGZIC - mission is the development of industry, involved in national drug policy. Service of IP.

Different directorates - pharmaceutical services. Mandate includes phytomedicines. Four phytomedicines are already developed.

- Forest : Money paid for regeneration activities.
- National Institution - biotechnology.
- Directorate of Environment.
- The universities.

There is an enabling environment for the development of herbal medicines. However, there is a lack of collaboration between different institutions and researchers as well as a lack of funds.

Session 12

Topic : Cosmetics and Essential Oils, and Biotrade.

Speaker: Dr. Lisa Messerole

Dr. Messerole presented a paper on the "Clinical uses of essential oils." *Mentha piperitae folium* is an example of a plant rich in essential oil. An overview of disease trends, especially in the U.S., was given with a view to establishing the potential importance of essential oils in the health care system. Hospital and respiratory infections, resistance to antibiotics and the presence of resistant strains, even in infants, are serious problems. Other problems include non-infectious diseases such as leukemia, chronic pneumonia, asbestos dust poisoning and other occupational hazards. The presentation reviewed the opportunities for essential oils in health care, including agents that promote healthy intestinal flora, immunomodulators, anti-oxidants to reduce cell degradation and adaptogens.

Important properties of essential oils include having good transdermal absorption and not leaving smear. They are known to have activity on the respiratory, urinary, nervous, digestive, endocrine, circulatory and immune system as well as the skin. Though they are known to have biological activities such as anti-inflammatory and anti-allergic effects, they seem to be most widely used worldwide as antimicrobial agents.

Research in essential oil therapeutic effects.

- Some are found to have antifungal effect (Egypt).
- Oil of bitter orange - for skin rash.
- Some oils for treating headache.
- Some act as preservatives in products in which they are included.
- Found that an oil pepper tree has antimicrobial (antibacterial) effect. 1993.
- Citronella and citral - found to have anti-allergic effect.
- Peppermint and sesame oil - antispasmodic.

Beauty products.

Essential oil needed is small quantity in preparation for acne. Oils from ocimum and witch hazel (anti-inflammatory).

Clinical application.

- Proper identification of plant is needed to avoid unwanted action, e.g. balm for heart massage.
- Use a large quantity of plant material to extract a small quantity of oil.

Quality assurance : Care should be taken in selection of the exact oil required.

Safety concerns : Side effects of the oil should be noticed. Some are known to have allergic reactions such as phototoxicity.

Evaluation of development potential for medicinal and tonic plants.

Problems :

- Access to raw material.
- Sustainable harvesting and production.
- Complexity of quality control (multi-components of these oils).

- Projected consumer.
- Profit potential.
- Availability, affordable, efficacy of these products.

There is a growing international market and acceptability of herbal products in areas of:

1) Body care and cosmetics.
2) Veterinary uses.
3) Insect repellant.
4) Medical aromatherapy.

Some herbal preparations which contain essential oils like ginger play a role in the world health economy. During discussion, there was a comment from the audience (Dr. Gericke), that a chemical compound - 1,8 cineole - in some essential oils could be used as standard for products used in asthma therapy.

Topic: Role of Medicinal Chemistry in Development of Natural Products Drugs

Speaker: Dr. Efange

Dr. Efange was involved in the synthesis of an antiviral substance which is now being developed as a radio-sensitive agent in liver cancer without his acknowledgment. The Iboga plant found in Cameroon and Gabon has a number of uses in traditional practice. Most of these uses relate to neurological activity, e.g. alertness, hallucination, aphrodisiac. A drug addict experimented with Ibogaine, found that it eliminated his craving for heroin, and patented it to the exclusion of either Gabon and Cameroon. He along with his collaborators have synthesized a compound with similar activities to Ibogaine (in terms of reversal of drug addiction) although with a different chemical structure. They have applied for a patent for this to the exclusion of Gabon and Cameroon.

Based on the two cases cited above, it was emphasized that coordination is crucial in our development strategy if we are to remain in control of our bioresources. Experts such as lawyers and pharmacists should be used to help understand the implication of the actions we take in terms of information release. When asked what we can do to prevent being left out by people who take extracts/compounds studied here and modify them into drugs with different structure, he said that there is little we can do about it, since the drug is basically different from our initial discovery. He said we should rather ensure that we take all the precautions before disclosing information be it in terms of structure or process.

Prof. Iwu added that care should be taken not to keep information or materials away from others for too long as this might drive them to go ahead with development without our contributions.

Topic: Economic Value Assessment of Forest Species

Speakers: Iwu, Nwaeze and Wirmum

This project was carried out in order to obtain the actual economic value of bioresources to the local people. Most of the previous assessments were inadequate since they did not take into consideration the value which the indigenous peoples placed on the items. This study was ethnocentric, thus allowing for actual values to be placed on the resources. So far the rapid appraisal tests have been conducted, and the results show that community forests are very useful for family survival, e.g. utensils for preparing food, which might have been overlooked in other types of surveys. Major economic species have also been identified for other uses.

This study is being conducted in Cameroon and Nigeria. Plots were assigned in each location for detailed studies and monitoring of the effects of various activities on biodiversity. One result was the observation that timber cutting, which had always been assumed to destroy biodiversity, if well-spaced and in low density does not affect biodiversity but rather tree density.

He concluded that it was a useful study since it puts actual value on the plants and could even provide useful exchange of information between communities resulting in enhanced economic value of the bioresources. Nat Quansah added that this type of study would give the people a strong reason for conserving their biodiversity, since they would be made aware of its value to them. On the issue of bush fires, the speaker was of the opinion that the natural ones were good. In some cases, it was even necessary for the flowering of some plants. A contributor also mentioned that the American Indians used it to control their natural habitat.

Dr. Claire Wirmum added that the study was useful in identifying extinct or rare plants since the indigenous people gave the information by themselves. In response to a question, it was stated that comparative plots were also included in the study.

IV. COMMUNIQUE AND RECOMMENDATIONS

The training workshop on Bioprospecting and Strategies for Industrial Exploitation of Medicinal and Aromatic Plants was held at the Nike Lake Resort Hotel Enugu, Nigeria. The workshop was declared open by the military administrator of Enugu state, represented by Mr. R. Okonkwo, Director General, Ministry of Trade and Industry.

Following the opening ceremony, the workshop commenced by reviewing the global perspectives of bioprospecting. The role of The International Center for Science and High Technology (ICS) [an agency within UNIDO] in the development and application of science and technology for industrialization was discussed in relation to bioprospecting for pharmaceutical industry. Industrial exploitation of medicinal and aromatic plants is intricately related to the overall development and environmental policies of a country. Furthermore, the sustainability of industrial production is dependent on the availability of raw materials. Bioprospecting, therefore, is a necessary activity undertaken to formulate a national plan for industrial exploitation of the plants. Bioprospecting is not only a screening activity for genes, species and ecosystems but also an activity evaluating the sustainability of industrial exploitation of these resources. The role of agrotechniques for domestication and propagation and of biotechnology for assisting in the production of raw materials and products must be examined carefully and taken into consideration. National policies for development of rural areas have to be reviewed in light of the fact that medicinal and aromatic plants are of great importance in health systems of these areas as well as having a high potential in international trade.

Three key issues were discussed. These were:

- In-country research and development through cooperative agreements, involving capacity building, collaboration and partnerships, and strategic business alliances.
- Materials Processing and Product development.
- International Bioprospecting Arrangements.

Unfortunately, while bioprospecting per se has been addressed to some extent, little or nothing has been done for the other two concerns. With regard to bioprospecting per se, it was noted that there were three key issues that required attention:

- Sustainable sources of raw materials.
- Material processing.
- Benefit sharing.

Subsequent discussions addressed other issues such as intellectual property rights (IPR), ownership and commercialization of medicinal and aromatic plant products and their processing. It was stressed that laws are dynamic and not static. Particular emphasis was placed on laws relating to IPR and patents. A review of the existing legislation revealed that most African countries do not have appropriate laws to cater to the provisions of the Convention on Biodiversity (CBD), including bioprospecting. It was pointed out that individual countries should be encouraged to take legislative measures that will create an enabling environment for sustainable utilization of their biodiversity, such as strengthening IPR laws. Harmonization of such laws within the continent is necessary for a common regional position on the management of Africa's biological and ecological resources. It was noted with concern that most laws in Africa tend to be punitive. In order to encourage community participation in this endeavor it is necessary that the laws should be formulated after a transparent and participatory discussion with all stakeholders and incentives should be provided.

Country reports and projects were presented and discussed. These included reports from Cameroon, Ethiopia, Gambia, Ghana, Guinea, Kenya, Madagascar, Mali, Nigeria, South Africa, Uganda and the United States of America. It became apparent that in all countries there is a need to encourage involvement of universities and research institutions. This will ensure that the necessary knowledge required for the conservation and sustainable utilization of biodiversity is available. Standardization of phytomedicines is necessary for quality control, process control, dosage and the law. The relevance of

the U.S. Pharmacopoeia and the African Pharmacopoeia was highlighted.

RECOMMENDATIONS:

- The service coverage of the ICS/UNIDO should be expanded to include pro-active capacity building and technology transfer in the field of industrial utilization of medicinal and aromatic plants.
- African countries must enact, as matter of urgency, appropriate and adequate legislation that would be conducive to conservation and sustainable utilization of their biodiversity. Emphasis should be laid on enforcement of these laws.
- The workshop recognizes the important role of the Scientific, Technical and Research Commission of the Organization of African Unity (OAU/STRC). The workshop thus strongly recommends that the role of OAU/STRC should be strengthened with the express aim of formulating a harmonized and enforceable African position on conservation and sustainable utilization of biodiversity.
- African countries must take urgent action to ensure adequate capability and capacity of human resources. A particular effort must be made towards increasing public awareness on the importance of medicinal plants and their conservation and training or mounting public enlightenment programmes within the local population to recognize IPR issues. This is especially true for the direct users such as traditional medical practitioners, scientists and institutions, national agencies and industry. Concise national patent information policies should be formulated.
- Models of various aspects of bioprospecting including benefit sharing and commercial utilization should be studied during the process of developing national policies on conservation and sustainable utilization of biodiversity.
- The workshop notes with great concern the lack of facilities for carrying out standardization and toxicological evaluation of medicinal and aromatic plants in Africa. The workshop thus strongly recommends that mutlilateral institutions such as the United Nations Industrial Developement Organization, the Global Environmnetal Facility and OAU/STRC should find mechanisms to rectify this situation.
- Recognizing that a considerable number of medicinal plant products in various formulations are already available in the market and are in general use, the workshop strongly recommends that such medicines and preparations should be standardized in the shortest possible time.
- Noting that information exchange in the field of African medicinal and aromatic plants within Africa is extremely limited, the workshop strongly recommends that OAU/STRC should reactivate the publication and dissemination of The Journal of African Medicinal Plants. The workshop further recommends that OAU/STRC should revise the African Pharmacopoeia as soon as possible.

V. LIST OF PARTICIPANTS

BDCP/ICS/UNIDO WORKSHOP ON BIOPROSPECTING AND STRATEGIES FOR INDUSTRIAL EXPLOITATION OF MEDICINAL AND AROMATIC PLANTS

S/N.	NAME	COUNTRY	AFFILIATION
1.	Wirnum Clare	CAMEROON	Mefopla. B.P.5164 Nkwen Cameroon.
2.	Tchukangoua Andre	CAMEROON	Younde/HINDIC Ministry of Industrial and Commercial Development. Fax: (237) 22 2704.
3.	Rose Abondo	CAMEROON	Center for Research and Production of Phyto-Cosmetics and Medicines "LE CABAS" P.O. Box 2097, Younde Ministry of Public Health Directorate of Pharmaceutical Services. Tel/Fax: (237) 224144
4.	Medhin Zewdu	ETHIOPIA	Biodiversity Inst. P.O.Box 30726, Addis Ababa, Ethiopia. Tel: 251-1-612244, Fax 251-1613722,
5.	M. K Cham	GAMBIA	Pharmaceutical Sciences Dept. of State for Health, The Gambia. Fax:(220) 22 58 73
6.	J. Pearce-Biney	GHANA	PharmaHealth Centre P.O.Box 9507, Kia

			Accra - Ghana. Ph/Fax : 233-21 - 220848
7.	E. Barnes	GHANA	Ministry of Env. Science & Tech. P.O. Box M.232, Accra, Ghana. Tel:(233 21)780305/303016. Fax: 666828 barnes @africaonline.com.gh
8.	A. A. Oteng-Yeboah	GHANA	Dept. of Botany. Univ. Of Ghana P.O.Box 55 Legon, Ghana. Fax 233 21 500306, E-mail Balme @ ug. Gh. Apc. org
9.	Mamadou Foula Barry	GUINEA	BDCP -Guinea University of Canakry. B.P. 1147, Conakry Guinea. Fax: 224- 41- 9880 Fax: 224- 41- 1414
10.	Piergiorgio Stipa	ICS-UNIDO	Via Grignano, 9-34014 Trieste - Italy. Tel:39-40-224-572 Fax: 39-40-224-575.
11.	Enrico Feoli	ICS-UNIDO	Via Gargnano, 9-34014 Trieste - Italy. Tel: 39-40-224-572 Fax: 39-40-224-575.
12.	Lucas O. Sese	KENYA	Kenya Industrial Property Office P. O. Box 51648 Nairobi, Kenya. Tel: 254 -2- 252453

			Fax: 254 -2- 219430
13.	Deborah Kioy	KENYA	Univ. of Nairobi P. O. Box 19796, Nairobi, Kenya Tel: 254-2-726770 Fax: 716961
14.	Nat Quansah	MADAGASCAR	Independent Researcher Villa Manongarivo. Lot 11k 21FP Soavimasoandro, Antananarivo 101, Madagascar. Tel: 261-2-421-44, e-mail: quansah @ bow.dts.mg.
15.	Flabou Bougoudogo	MALI	Dept. Medecine Traditionelle 1 NRSP BP1771 Bamako - Mali Fax: (223)- 23-19 -99 Tel: (223) - 22-42-31
16.	Lola Akeju	NIGERIA	BDCP Abuja, Nigeria. Phone: 09-5231617
17.	R. A. Boroffice	NIGERIA	NASENI 9, Kofo Abayomi St, Victoria Island, Lagos Nigeria.
18.	Mshana Robert		OAU/STRC PMB 2359 Lagos, Nigeria. Tel: 234-1-263 3430 Fax: 234-1- 263 6093 OAUSTRC.Lagos @ rcl.dircon.co.vk

19.	G. I. Adams	NIGERIA	NASENI/Lagos 9, Kofo Abayomi Street, Victoria Island, Lagos, Nigeria. Tel: 01-619659/614759.
20.	Patricia Johnson	NIGERIA	Dept. of Pharmacology University of Jos. P.O.Box 2084, Jos. Plateau State Peejay @ Unijos.Edu. Ng.
21.	C.O.Diribe	NIGERIA	Enugu State University P.M.B. 01660 Enugu - Nigeria. diribe @ infowebiabs.abs.net. Fax 234-42255576
22.	F. Okwuasaba	NIGERIA	University of Jos. Dept. of Pharmacology. Jos, Nigeria.
23.	S. Inya-Agha	NIGERIA	University of Nigeria Faculty of Pharmaceutical Sciences U.N.N. Nsukka, Nigeria.
24.	J. L. C Ibuzo	NIGERIA	Forestry Dept. HQ Forestry Dev. & Investigation branch Awka.P.M.B 5073 Anambra State, Nigeria
25.	K. C. Nnadozie	NIGERIA	BDCP Lagos. 1 Tinuade St. Ikeja, Lagos, Nigeria. Tel: 234-1- 5834878 Fax: 234 - 1- 5834998 E-mail: Kent @ netlane.com

26.	Tony Elujoba	NIGERIA	O.A.U. Ile Ife Faculty of Pharmacy, O.A.U. Ile Ife, Nigeria.
27.	Zebulon S.C. Okoye	NIGERIA	Faculty of Med. Science, University of Jos. Jos, Nigeria.
28.	O. O. Kunle	NIGERIA	National Institution for Pharm. Research and Development (NIPRD) P.M.B. 21, Abuja, Nigeria. Fax: 09 - 5231043
29.	E. Aka Kyrian	NIGERIA	National Centre for Remote Sensing (NCRS), Jos, Nigeria.
30.	A. O. Salu, (Mrs)	NIGERIA	Nigerian Law School N. L. S. Victoria Island, Lagos, Nigeria. P.M.B 12610 Lagos, Nigeria. Tel: 613144
31.	A. Aliyu Bindawa	NIGERIA	BDCP-Abuja FEPA P.M.B 265, Garki, Abuja Nigeria.
32.	Oma Obijiofor	NIGERIA	BDCP 11303 Amherst Ave, Suite 2 Silver Spring, MD 20902. Phone:(301) 962-6201. Fax: (301) 962-6205.

33.	Ossai Nwaenyi	NIGERIA	Orba Nsukka, Nigeria
34.	Bunmi Onayade	NIGERIA	Obafemi Awolowo University Fac. Of Pharmacy Ile-Ife, Osun State, Nigeria aonayade@oauife.edu.ng
35.	Maurice M. Iwu	NIGERIA	BDCP 11303 Amherst Avenue, Suite 2 Silver Spring, MD 20902, USA
36.	Cosmas N. Obialor	NIGERIA	BDCP P.O. Box 2547, Owerri Imo State, Nigeria Phone: 234-83-234129
37.	E.N. Sokomba	NIGERIA	BDCP 1 Tinuade Street, Off Allen Avenue, Ikeja Lagos, Nigeria. Tel: 01-4970663/800140-4, Tel/Fax: 689050.
38.	I. C. A. Okorie	NIGERIA	BDCP 110 Aku Road, Nsukka. Enugu State, Nigeria. Tel: 042-770726/770724.
39.	Joy C. Anyiam	NIGERIA	BDCP 1 Tinuade Street, Off Allen Avenue, By First Bank, B/ S, Ikeja Lagos. Tel: 01-4970663

40.	C. Ezeugwu	NIGERIA	BDCP 110 Aku Road, Nsukka. Enugu State, Nigeria. Tel: 042-770756.
41.	Justin Onuorah	NIGERIA	BDCP 1 Tinuade Street, Off Allen Avenue, P. O. Box 13940 Ikeja,Lagos. Tel: 01-4970663
42.	Chike Onyechere	NIGERIA	BDCP NSUKKA.
43.	Chika Onyeanusi	NIGERIA	BDCP NSUKKA.
44.	Ugochukwu Uba	NIGERIA	BDCP 14. Abomini Cresent Independence layout, Enugu, State. Tel: 042-453168.
45.	Nigel Gericke	SOUTH AFRICA	P.O. Box 937 Sun Valley 7985 South Africa Phone/fax: 27-21-789149 npg-nbd@iafrica.com
46.	Bwogi R. Kanyerezi	UGANDA	Kawaga Ltd. P.O.Box 3973 Kampala Uganda. Tel: 256 41-255006/255098 Fax: 254-2-219430

47.	Godwin Sentongo	UGANDA	E. S. T. A. P. O. Box 3706 Kampala Uganda. Tel: 256 - 41- 231022 Fax: 256 - 41-345580
48.	Simon Efange	U. S. A.	Univ.of Minnesota Dept. Of Radiology VMHC box 292 420 Delaware st. SE Minneapolis, MN 55455, USA Phone: (612) 626 - 6646 Fax: (612) 624 - 8495
49.	Katy Moran	U.S.A	Healing Forest Conservancy 3521 S St, NW Washington DC, 20007 USA. (Moran HFC @ AOL.COM) Tel & Fax. 202 - 333 - 3438.
50.	Julie Chinnock	U.S.A	Shaman Pharmaceuticals 213 E Grand Ave. S. San Francisco, CA 94080 USA Tel: (415) 952-7070 Jchinnock @ shaman.Com
51.	V. Srini Srinivasan	U.S.A	U.S Pharmacopiea 12601 Twinbrook Parkway Rockville MD 20852 USA Tel: 301-816-8334 Fax: 301-816-8373 E mail: VS @ USP. Org
52.	David Stephenson	U.S.A	Kaffa Dev. Assoc./ Wagenlander & Assiciates 3888 W. Grambling Dr. Denver,CO 80236-2444, USA Tel: 1-303-832-7920; 1-305-922-7001. Fax: 1-303-922-8535, E-mail: Davids 23, @ aol.com

53.	Angela Duncan	U.S.A	BDCP 3030 Sansalvador Waterloo, Ia 50702, USA. Phone: 319 233 - 3245 E-mail: Hepar @ aol.com. 319233 - 0048 (fax)
54.	Lisa Messerole	U.S.A	BDCP 4836-38th Ave, Seattle WA 98105 USA. Tel: (206)-527-6355/526-1339

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PROGRAMME

SUNDAY 21st SEPTEMBER 1997

1200-1900	Arrival/ Registeration

MONDAY 22nd SEPTEMBER 1997

0800-1000	Registeration
1000-1100	Opening Ceremony - by Military Administrator of Enugu State represented by Director General, Ministry of Trade and Industry
1100-1130	Overview of ICS-UNIDO Activities and Programmes - Enrico Feoli
1130-1140	Discussion
1140-1200	Coffee/ Tea break

Session One: Overview of global bioprospecting projects

Chairman:	Enrico Feoli
Rappateurs:	Deborah Kioy Simon Efange
1200-1230	Overview of Global Bioprospecting - Maurice Iwu
1230-1240	Discussion
1240-1400	Lunch

Session Two: Policy and Legal Framework for Bioprospecting

Chairman:	Robert Mshana
1400-1430	Intellectual Property Protection, Ownership and Commercialization of Medicinal and Aromatic Products and Processes - Lucas Sese
1430-1440	Discussion
1440-1540	Contribution by workshop participants Need for Sustained Utilization, Development and Commercialization of Plant Medicine - James Pearce-Biney Herbal Medicine Practice in Uganda - Godwin Sentongo
1540-1600	Discussion
1600-	Social/ Informal get-together

TUESDAY	**23rd SEPTEMBER 1997**
Session Three:	**Implementation of the UN Convention on Biological Diversity** (Panel Discussion)
0900-1000	E.P.D Barnes Lucas Sese K.C. Nnadozie
Session Four:	**Computerized Information systems and bioprospecting**
	Chairman: P. Iwe Akubue Rappoteurs: Kent Nnadozie Medhin Zewdu
1000-1030	Resource Systems in the use of medicinal and aromatic plants - Enrico Feoli
1030-1040	Discussion
1040-1100	Policy Initiatives on Bioprospecting in Ghana: Ministry of Environment, Science and Technology - E.P.D. Barnes
1100-1110	Discussion
Session Five:	**Sustainable sourcing of medicinal and aromatic plants**
1110-1140	Ex-situ conservation of indigenous African Plant Biodiversity - Alfred Oteng-Yeboah
1140-1150	Discussion
1150-1210	Bioprospecting and the Conservation of Biological Resources - Nat Quansah
1210-1220	Discussion
1220-1240	Information on Gambian Pharmaceutical Service and Regulatory Conditions - Momodou Cham
1240-1250	Discussion
1250-1400	Lunch
Session Six:	**Tools of the Trade -1: Case studies of different models for the commercialization of biodiversity**
	Chairman: Elijah Sokomba
1400-1430	Ethnobotanical Collection and Tracking methods for Medicinal Plant Research - Julie Chinnock
1430-1440	Discussion

1440-1520	Contribution by Workshop participant BDCP Program in Guinea - Barry Foula Herbal Medicine: HIV Therapy in Uganda - Bwogi Kanyerezi
Session Seven:	**Tools of the Trade 2: Case studies of different models for the Commercialization of biodiversity**
1520-1550	Returning Benefits from Ethnobotanical Drug Discovery to Native Communities - Katy Moran
1550-1600	Discussion
1600-1620	Tea/ Coffee break
1620-1700	Contribution by workshop participants Medicinal Plants for Industrial Exploitation - Deborah Kioy State of Bioprospecting in Mali - Flabou Bougoudogo

WEDNESDAY SEPTEMBER 24, 1997

Session Eight:	**Process Technology for the Production of Phytomedicines** Chairman: Lisa Messerole Rappateurs: Julie Chinnock Momodou Cham
0900-930	Key Legal and Ethnoecological Components of a Bioprospecting Agenda -David Stephenson
930-940	Discussion
940-1010	Role of Botanical Products in the Health Care System and Scientific Issues in the Development and Establishment of Public Standards for Botanicals - V. Srini Srinivasan
1010-1020	Discussion
1020-1110	Pharmacognostical Standards for Crude Drug - Tony Elujoba
1110-1120	Discussion
1120-1140	Tea/ Coffee break
1140-1210	Process Technology for Production of Phytopharma Medicines - R. Nasipuri/ Kunle O.O.
1210-1250	Contributions by workshop participants Phytomedicine Research - Central and Eastern Nigeria - F. Okwuasaba

	Ethnobotany and Economic Evaluation of Plant species in Bafut, Sabga and Oku (NWP of Cameroon) - Clare Wirmum
1250-1400	Lunch
Session Nine:	Pharmacological and Clinical Considerations
	Chairman: Alfred Oteng-Yeboah
1400-1430	Pharmacological and Clinical Issues Related to Commercialization of Phytomedicine - P.I. Akubue
1430-1440	Discussion
1440-1510	National Agency for Science and Engineering Infrastructure - R. Boroffice
1510-1520	Discussion

THURSDAY **SEPTEMBER 25, 1997**

Chariman: Piergiorgio Stipa
Rapoteurs: Patricia Johnson
Nat Quansah

Session Ten: **Technology Management**

0900-1000	Business Development I - Nigel Gericke
1000-1020	Discussion
1020-1040	Tea/ Coffee break
1040-1140	Business Development II - Maurice Iwu
1140-1200	Discussion
1200-1230	Case Study "Le CABAS" Center for Research and Production of Phytomedicines and Cosmetics - Rose Abondo
1230-1240	Discussion
1240-1400	Lunch

Session Eleven: **Panel**

1400-1600

A: Policy Considerations, Access, IPR and Benefit sharing (Sese/ Stephenson)
B: Conservation and Sustainable sourcing (Quansah/ Obialor)
C: Biotrade and Phytomedicine (Nigel/ Stipa)

1600-1620	Tea/ Coffee break
1620-1700	Contributed papers by workshop participants Research and Development Activities on Medicinal and Aromatic Plants in Ethiopia - Medhin Zewdu
	Remote Sensing and Application to Bioprospecting in Nigeria - Aka Kyrian
	Regulatroy Bodies in Cameroon - Andre Tchukangoua

FRIDAY SEPTEMBER26, 1997

Session Twelve: Cosmetics and Essential Oils and Biotrade Opportunities

Chairman: Tony Elujoba
Rappoteur: Lola Akeju

0900-930	Cosmetics and Essential Oils and Biotrade Opportunities - Lisa Messerole
930-940	Discussion
940-1110	Chemical synthesis of medicinal and aromatic plants - Simon Efange
1110-1120	Discussion
1120-1140	Tea/ Coffee break
1140-1210	Economic Value Assessment of Forest species - Iwu, Nwaeze, Wirmum
1210-1220	Discussion
1220-1400	Lunch
Session Thirteen:	Plenary - Consideration of Panel Reports and Recommendations
1400-1600	Discussion