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Expert Group Meeting on the Promotion and
Development of the Industrial Utilization
of Medicinal Plants in Africa*
Brazzaville, Congo
20-23 November 1995

REPORT**

* Jointly organized by the United Nations Industrial Development Organization (UNIDO) and the World Health Organization (WHO), Regional Office for Africa (WHO/AFRO) in cooperation with the Government of the Congo.

** This document has not been edited.

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I. INTRODUCTION

Industrial Co-operation and Consultations Service of the United Nations Industrial Development Organization (UNIDO) enhances global and regional industrial co-operation through the promotion of partnerships between various entities concerned with industrial development in developed and developing countries. In doing so, special emphasis is placed on innovative institutional partnerships and South-South co-operation.

The Expert Group Meeting (EGM) on the Promotion and Development of the Industrial Utilization of Medicinal Plants, jointly organized from 20 to 23 November 1995 by UNIDO and WHO in co-operation with the Government of the Congo as part of the follow-up to the recommendations of the Regional Consultation on the Industrial Utilization of Medicinal and Aromatic Plants in Asia and the Pacific which was held in Vienna from 5 to 8 July 1993.

The African countries are endowed with a very rich medicinal flora. However, a number of them export plant raw materials to industrialized countries for processing. Thus, special emphasis was put at the Regional Consultation on the industrial-scale utilization of medicinal plants to increase the availability of herbal medicine and drugs derived from medicinal plants for the health of a large segment of the world's population. In this respect, the Regional Consultation underlined the need for a systematic and integrated approach to the development of agro-based medicines. Such an approach would include the adoption of coherent policies and measures at the national, regional and international levels towards systematic cultivation, improved processing and production technologies, quality standards, studies on pharmacological evaluation, development of information networks and research, regulatory and registration arrangements, human resources development and ways and means to enhance value-added of raw materials and products and thus encourage the establishment of small scale industries with impact on national and rural economy.

The Regional Consultation placed strong emphasis on the need to strengthen sub-regional, regional and international cooperation in the industrial utilization of medicinal plants and recommended in particular that periodic consultations should be organized at regional levels with the aim of further developing the sub-sector. The Expert Group Meeting will be held in that context and is expected to pave the way for the next Consultation on the industrial utilization of medicinal plants which should be held in Africa in 1996, as recommended by Regional Consultation.

II. OBJECTIVES

The objectives of the meeting were:

- To provide governments, industry and other interested entities in the African Region, with assessed information on development potential of industrial utilization of medicinal plants and thus to increase awareness of the potential for the local manufacture of plant-based medicines.
- To provide an opportunity to discuss and highlight the main problems faced by developing countries in undertaking and executing an integrated approach for the development of the sub-sector.
- To serve as a forum to discuss initiatives leading to the development of indigenous skills, technology for processing and quality assurance.
- To provide an opportunity to discuss mechanisms for co-operation in the establishment of R & D capabilities and development of joint R & D activities in selected disciplines of the sub-sector.

- To highlight the needs for regulatory arrangements for introducing plant derived medicines and mechanisms for their introduction in health care systems.

- To identify already tested and readily marketable drugs and molecules that have proved their efficacy in the treatment of the commonest diseases.

- To promote international co-operation and discuss related measures for its promotion in mutually beneficial areas with the aim of promoting economic exploitation of local resources.

III. ORGANIZATION OF THE MEETING

The Expert Group Meeting (EGM) was held with the active participation of 21 specialists in the processing and development of plant-based products and R & D on medicinal plants of 18 African countries (list of participants in Annex). Four resource persons, Special Technical Adviser on medicinal and aromatic plants at UNIDO Headquarters, WHO Regional Adviser on traditional medicine and assistant executive secretary of the OAU/STRC shared their experiences with the participants. Each country participant presented a brief account of the current status of activities on the medicinal plant research, usage and production and the constraints they faced in the development of this sub-sector and indicated their requirements to improve the industrial utilization of medicinal plants through technical assistance from development agencies and cooperation with other countries.

The meeting was conducted in English and French with simultaneous translation from one to the other.

IV. INAUGURATION

Dr. D'Almeida, Director of Programme Management of WHO for Africa welcomed participants on behalf of the Regional Director. He stated that today 75 to 90% of the African population rely on traditional medicine to solve their health problems and that nearly 33% of drugs found on the market are derived from plants originated from the tropical regions of developing countries.

For these reasons we approve the objectives that you have set for yourselves, including:

- the identification of already tested and readily marketable drugs and molecules that have proved their efficacy in the treatment of the commonest diseases;

- the resolution of problems that the countries are facing in this sector.

Then he declared open the meeting.

In his remarks, the Senior Industrial Development Officer of Industrial Cooperation and Consultations Service, Investment and Technology Promotion Division, welcomed the participants on behalf of UNIDO and recalled the main objectives of the meeting. He urged the participants to concrete contribution to the discussions and put forward action-oriented recommendations and proposals. He paid tribute to the genuine spirit of cooperation demonstrated by WHO in co-organizing the meeting with UNIDO. This cooperation should be further strengthened particularly for the implementation of follow up activities and the recommendations of the meeting.

V. SELECTION OF BUREAU

Office Bearers

The following were nominated:

Chairman: Prof. C.O.N. Wambebe
Director-General and Chief Executive,
National Institute for Pharmaceutical Research and Development,
Abuja. Nigeria.

Vice-Chairman: Prof. J. Noel Gassita,
Universite Omar Bongo,
Faculty de Medicine,
B.P. 100, Libreville, Gabon

Rapporteurs: Professor Penge On'okoko
Faculté Pharmacie
Universite de Kinshasa
Zaire

Mr. Montfort Lutamyo Mwanyambo
Scientific Officer
Gardens of Malawi
National Herbarium and Botanic
Zomba
Malawi

VI. ADOPTION OF THE AGENDA

The following agenda was adopted:

1. Opening of the meeting.
2. Selection of Bureau.
3. UNIDO's technical cooperation activities in the area of medicinal plants - Special Technical Adviser, Chemical Industries Branch, Industrial Sectors and Environment Division.
4. Research, Development and Production of Plant-based medicaments in Africa: A case study in Rwanda - Prof. Luc Van Puyvelde.
5. WHO activities in the area of traditional medicine in Africa - Dr. M. Koumaré.
6. Country presentations.
7. Processing Technologies and GMP for the production of plant-based medicines - Prof. Chen Yingjie.
8. Evaluation of the efficacy and safety of herbal medicines and development of plant-based drugs - Prof. B.N. Dhawan.

9. Regional overview on the industrial utilization of medical plants for health care systems in Africa - Prof. M. Gundidza.

10. Quality control and marketing authorization of African traditional drugs - Dr. M. Koumaré.

11. Presentation by the Representative of the OAU/STRC - Mr. A. L. Mbiele.

12. Group discussions.

13. Closing session.

VII. SUMMARIES OF PRESENTATIONS OF RESOURCE PERSONS AND DISCUSSIONS

1. UNIDO's technical cooperation activities in the area of medicinal plants - Special Technical Adviser, Chemical Industries Branch, Industrial Sectors and Environment Division

Due to some inherent limitations of Traditional Medicine including composite constituents, unsuitable models and evaluation issues, development of Traditional Medicine was not attractive to the pharmaceutical industry. However, current encouraging global trends resulting from increased awareness, free market economy and acceptability suggest that the industrial utilization of medicinal plants would be adopted and implemented in most developing countries. Already, medicinal plant products are utilized as phytopharmaceuticals, galenicals, excipients, health foods, herbal teas, herbal medicines and intermediates.

UNIDO programmes in this sector include consultation, promotional, exploratory and development assistance. Country specific programmes take cognisance of ecological factors, existing biodiversity, indigenous technical expertise and government political will.

Agrotechnology embracing yield, domestication, seed banks, organic cultivation, harvesting technology and genetic engineering is a strategy pursued by UNIDO in collaboration with FAO. Process technology transferred enhances quality, evaluation, authentification and standardization of isolated pure compounds, intermediates and galenicals.

Development of plant based products progress from laboratory to bench and pilot scale. However, the last phase has been hindered by inappropriate process technology which had delayed the transfer of R & D findings to the industry. UNIDO developed a multi-purpose pilot plant which has effectively filled the missing link between R & D findings and the industry.

UNIDO projects involve total quality management, validation for ISO 9000 series, ISO 14000 series, human resource development, marketing, R & D investigations, software development, setting up national data-base registration, property rights, industrial information and export promotion. UNIDO modality for project implementation includes specified outputs, activities and inputs.

2. Research, Development and Production of Plant-based medicaments in Africa: A case study in Rwanda - Prof. Luc Van Puyvelde

In Rwanda, first organized research on traditional medicine and medicinal plants started in 1971 at the Faculty of Medicine at the National University of Rwanda which led to the creation of a research centre in 1980: CURPHAMETRA (Centre de recherche sur la Pharmacopée et la Médecine traditionnelle).

The principal aim of CURPHAMETRA was the production of plant-derived drugs. To achieve this aim, CURPHAMETRA adopted the following workplan:

- Integration of traditional medicine into the primary health care system.
- Production of medicaments starting with well-known medicinal plants, i.e. "Official Medicinal Plants".
- Production of solvents and excipients.
- Study of economically important plants.
- Research and development on new drugs.

An account of the development of pant based products at Curphametra was presented. Samples of the products were shown.

CURPHAMETRA produced several extracts from Officinal Medicinal Plants such as: tincture of *Datura stramonium*, *Eucalyptus globulus* and *Thymus vulgaris*, liquid extract of *Plantoyo cauccolata*, *Capsicum frutescent* and *Calendula officinalis*, as well as essential oils of *Eucalyptus globulus* and *Mentha sachacinensis*. With these extracts, several medicines were manufactured and commercialized: anti-cough solution and syrups, anti-spasmodic syrup, anti-rheumatic solution and an anti-inflammatory ointment.

From the research and development endeavour on modern traditional medicine several new products were developed including an anti-scabies solution and ointment, an anti-mosquito candle and ointment (already commercialized), an anti-mycotic ointment and a new pesticide.

The pilot plant was financed by a UNIDO project and the extension of activities by the Belgian Government.

3. WHO activities in the area of traditional medicine in Africa - Dr M. Koumaré

Since the second meeting of Directors of WHO collaborating centres in November 1987, the requests for the integration of traditional medicine in national health system, made by countries are increasing and the programme is trying to face adequately the challenge with the following objectives:

General Objective

To promote and develop the rational utilization of traditional medicine in order to contribute to the establishment of national health care system bearing in mind the peculiarity of socio-cultural environment of each country.

Specific Objectives

Role of traditional medicine in the organization and delivery of the general health care system (integration of the two health systems).

To support countries which so desire, in the formulation of relevant national policy and the elaboration of legal framework for the practice of traditional medicine and the use of standardized and licensed remedies and methods.

Studies and research on traditional medicine

To assess, the appropriate methods, traditional practices and remedies within the cultural setting concerned so as to identify and license those which are safe and effective.

Training in traditional medicine

To assist countries to improve the skills and knowledge of practitioners in both health care systems through complementary training.

Achievements

In its role of guidance and coordination, the WHO Regional Office for Africa took the following actions:

- Situation analysis made with the questionnaire filled by countries.

- Preparations of guidelines in three areas:

  - policy, programmes and structures;
  - study and research on natural medicinal substances and practices;
  - training;
  - support to countries in the three above-mentioned areas;
  - organization of workshop and contractual services;

Summary of discussions on above presentations of resource persons

Delegates asked questions or made comments on the three presentations. The issue of intellectual property rights emerged regarding the case study in Rwanda. It was explained that in one instance where information came directly from a particular traditional practitioner, the incumbent was included for monetary benefits. Further issues raised were safety of the plant products and the cost/benefit analysis of producing the plant based drugs. It was noted that safety was guaranteed since plants were selected from established pharmacopoeia and products were tested first on animals and later on volunteers. It was also learnt that the biggest problem was getting the products on the market since prescribing personnel, i.e. doctors, had to be convinced.

There was also great concern about lack of funding for research. It was suggested that countries should create research funds by dedicating a percentage of all import charges to the fund. Similarly, a levy could be put on all exports from the country. It was learnt that UNIDO can support, directly, private industry provided, if such requests are approved by the Government.

Delegates also wanted to learn if WHO Regional Headquarters had an existing data bank. It was learnt that software on medicinal and aromatic plants was being developed at WHO Regional and at NIPRD, Abuja, Nigeria; Napralert is also available for countries needs.

4. Processing Technologies and GMP for the production of plant - based medicines - Prof. Chen Yingjie

Medicinal plants contribute a great deal to the health care of people all over the world. Yet, many traditional medicines are still prepared by conventional methods in developing countries. The processing technology for extracting and formulating should be improved and modernized to produce standardized plant-based medicines which possess efficacy, safety, uniformity, stability and easy transport.

The major unit operations for extracting medicinal plants are extraction, filtration, distillation, evaporation and drying. The industrial equipment needed for the extraction operation are percolator, extractors and multifunction extractors. The polyvalent pilot plant unit for the distillation and extractor of medicinal and aromatic plants, designated by UNIDO, provides valuable reference models. The equipment for liquid - liquid extraction are the centrifugal extractor and the extraction tower. Vacuum evaporator, and vacuum thin layer evaporator are commonly used equipment for evaporation. Roller dryer, tray drying cabinet, spray dryer and freezing dryer are well used for the drying operation.

The major technological methods for extracting medicinal plants are aqueous extraction, water-alcohol method, alcoholic extraction, organic solvent extraction, acid-alkali method, resin method and the chromatographic method. The resin method is strongly recommended for production of plant-based pharmaceutical because of lower cost of production, lower energy consumption, higher purity of the

extract, lack of air and water pollution and absence of special safety requirements.

Quality assurance is of vital importance in manufacturing plant-based medicines. a good quality control laboratory should be established. All of raw materials, intermediates and finished products should be standardized and controlled according to standard specifications. All of manufacturing activities and R and D should follow GLP, GCP and GMP. R and D is very important in the promotion and development of industrial utilization of medicinal and aromatic plants. The major activities are selection of plants, chemical and biological studies, developing modern processing technologies, establishing quality control methods, standardization of raw materials, intermediates and finished products, investigation into new plant-based drugs derived from pure bioactive compounds, standardized extracts, clinical trials, etc.

Steps should be taken to prevent pollution in the industrial utilization of medicinal plants. Waste liquids and plant residues should be reprocessed into harmless or useful substances. Comprehensive utilization of medicinal plants is the best choice for waste disposal.

5. Evaluation of the efficacy and safety of herbal medicines and development of plant-based drugs - Prof. B.N. Dhawan

The presentation highlighted the factors responsible for increased interest in plant based drugs and the necessity of concerted research on traditional drugs as well as the endemic plants to develop new drugs. These drugs should be safer, easier to produce using environmental friendly technology and renewable resource and have better patient acceptance. Various steps involved in new drug development were discussed and the enormous cost and time involved were pointed out.

This could be significantly less in developing traditionally used drugs in a poorer acceptable to modern to modern health care programmes.

The major steps in biological evaluation include initial efficacy detection (lead generation), detailed follow up pharmacodynamic and pharmacokiretic studies and safety evaluation. This is necessary prerequisite to clinical studies.

Several types of screening programmes can be developed to detect activity. The prerequisites, objectives, organization and management of various types of screening programmes and incorporation of adequate quality control parameters was discussed.

The important of sticking to norms set by the Drug Regulatory Agencies for toxicity studies was stressed. The objectives, organization and test systems for acute, sub-acute and chronic toxicity, terralogenicity, malagenicity, carcinogenicity, and reproduction studies was described. The significance of appropriate dose levels (3 in most cases), duration of studies and selection of appropriate animal species was explained.

The second part of the presentation was devoted to brief discussion of various strategies developed by and utilized at CDRI for development of new drugs from natural products along with the highlights of appropriate case studies of successful outcomes. In many cases test systems have been modified to accept products of various grades of purity. Standard compounds are used for comparison wherever necessary, to generate quantitative data.

In order to find prospective leads the following approaches have been used:

(a) Broad based biological screens

Over 120 in vitro and in vivo test systems are employed and in most cases, 50 % Ethanolic extract is first tested. Active extracts are subjected to broadway linked chemical separation procedures to isolate and characterize active constituents.

Results with 4000 terrestrial plants and 600 massive products were presented. The procedure is best suited for endemic flora and massive products were presented. The procedure is best suited for endemic flora and massive organisms but new activity could be detected in traditional drugs also. Importance of botanical authentication and collection was schemed.

(b) Special tests for traditional drugs

Necessity of careful selection of preparations to be tested as well as appropriate test systems was pointed out and successful case histories of hypolifidemic (being marketed), hepaloprotective, antitenlomanial and specificated products were presented. It was clearly brought at that standardized extracts (containing specified amount of active constituents) was usually more effective, optimized the use of plant material, required simpler process technology and was preferable over pure constituents. More products are being marketed or in advanced stages of development.

(c) Special tests indicated by chemical structure

Results of tests on asclepin isolated from Asclepias curassavica with a cardenolide structure for cardiotonic activity were presented.

(d) Development of semi-synthetic compounds by lead optimization

Promising results of using artemisinine arteether against the malarial parasite falciparum malaria were described.

(e) Initial Clinical Trials

The indication, prerequisites and planning were discussed. It was pointed out that even slight variation in a traditional formulation necessitated toxicity studies and a non-traditional product cannot be directly clinical tested.

As a combined result of various approaches, over a dozen compounds have reached the market or clinical testing stage at CDRI.

In conclusion, two alternative approaches for study of traditional drugs with their pros and cons were presented and discussed. It was stressed that multidisciplinary expertise and team activity is a prerequisite of stressed that multidisciplinary expertise and team activity is a prerequisite of success. It is also necessary to identify national/regional priority diseases or plants and to concentrate efforts on those rather than on minor products. Special emphasis to endangered and endemic species was also necessary and the resource could be expeditiously exploited.

6. Regional overview on the industrial utilization of medical plants for health care systems in Africa - Prof. M. Gunċidza

An account of the current state of development of the industries based on medicinal plants in some african countries visited by the consultant was presented. Based on the findings, the consultant made some action oriented recommendations for the promotion and development of industrial utilization of medicinal plants in Africa, which were discussed during the group discussions on the recommendations of the meeting.

Education and training

There must be educational programmes on television, radio and other forums on the importance and economic value of medicinal plant products in all African countries. The teaching of natural medicine can also be incorporated in pharmacy and medical undergraduate curricula.

Training

Many African countries expressed the need for UNIDO to identify centres for training or organization of on-the-job training in Africa. To this end it is hereby being recommended that there should be two regional training centres, one in Southern Africa and the other in West Africa. The courses to be covered should include all aspects of natural medicine and the industrial utilization of medicinal plants.

Scale up Equipment

In many African countries there is no infrastructure and technology to manufacture basic equipment. It is therefore being recommended that each country with the help of UNIDO procures appropriate items of equipment such as stills, freeze-dryers, etc. Sophisticated equipment such as NMR, HPLC, GC, GC/MS, etc. can be installed at one or two institutions in Africa where samples from other countries can be sent for analysis.

Registration

It is recommended that medicinal plant products that satisfy basic minimum WHO standards for registration be considered for registration by appropriate health authorities in different African countries. It is also recommended that trained people in natural medicine be registered with the Health Professional Councils of all African countries so that they can practise natural medicine openly and without prejudice. Such practice should be regulated by Governing Boards.

Creation of National and Regional Associations of Natural Medicine

National and Regional Associations should be formed and entrusted with the following mandates:

- Information access
- Market access and development
- Research and development
- Quality assurance and certification
- Agronomic and business support service
- Business involvement and support
- Support facilities and infrastructure
- Creation of a databank
- Organization of workshops/seminars/symposia/conferences
- Publication of newsletter and journal

7. <u>Quality control and marketing authorization of African traditional drugs - Dr. M. Koumaré</u>

The presentation reminds the interest in traditional drugs; and indicates that the acceptance of these drugs by modern practitioners is hampered even today by scepticism stemming from the criticisms levelled against them for technical inadequacies. This stresses the need to evaluate them in order to promote their standardization and facilitate their authorization as well as their registration on national lists of essential drugs. It is therefore necessary to propose a suitable and an objective evaluation meythodology trying not to be too rigid or too slack.

It is recommended to take into account and quantify "estimated pharmacovigilance" through post-factum surveys and then supplement that with "real pharmacovigilance".

The fact that efficacy is linked to the notion of active ingredient should in no way imply any need for a "simple, pure and crystallized module". Since some tinctures are preferable to crystallized substances of the same origin, what matters most is to obtain a stable and reproducible galenical preparation. This applies, as well, to "improved traditional drugs" which will have to be instituted as

soon as the stage of "personalized therapeutics" is over.

Comparative clinical trials must be legally and officially more easily authorized than is the case at the movent. Technical evaluation of traditional medicine must be based on the following three areas:

- Identification and stability
- Safety
- Efficacy through comparative therapeutic tests

The following approaches for "Initiated people's drugs" and "Improved traditional drugs were proposed:

For Initiated people's Drugs

(i) On the legal and administrative levels.

Revision or preparation of a national drug policy, taking into account the promotion and development of traditional African cure. This policy has to be backed p by a legislative text on the quality control and marketing procedures .

(ii) On the technical level

Identification and stability

- Designation (finding a specific name if possible)
- Organoleptic natures (indicating at least three)
- Physicochemical nature (indicating at least three)
- Description of chemical constituents (indicate three and if possible make a chromatographic profile);

Safety

To the extent that it is not possible to observe the patient to whom the drug had been administrated, information (posology, side-effects etc.)given by the traditional healer will be taken into account for tolerancetest and clinical observation for 24 hours); this consists of oral administration at one go to a mouse, and, in proportion to its weight,of at least a dose that is 30 times the adult dose indicated by the traditional healer.

Efficacy

On the criteria for selection by exclusion of patients by the traditional healer will be used. Followed by the most characteristic clinical symptoms (three to five) and biological manifestations (two, if possible), during a given period with pre-and post-assessment (if possible, one taken midway of the indicated period).

In the case of malaria for example:

- positive clinical symptoms (temperature, stiffness, headaches, nausea, vomiting).
- positive biological manifestations (parasitemia, haemoglobin level).
- judgement will be based on the evolution of both clinical and biological symptoms found and on the possible side-effects.
- a statistical calculation using the Wilcoxon test will be used to confirm the results.

For improved traditional drugs

(i) On the legal and administrative levels
Measures to be taken are the same as those for the drugs by the initiated.

(ii) On the technical level
Identification and stability
Comparison of the characteristics of the candidate sample with those determined for the drugs of the initiated.

Safety

If improvement to the form has adversely affected the initial stability and/or the characteristics of the chemical constituents highlighted, an adult dose, proportionate to their weight, would be administered orally and for a period of seven days to a mouse or rat. The animals will be kept for at least three weeks under observation.

Efficacy

Criteria for selection by excluding patients will be those justified the research on the drugs by the initiated.

Comparison of the effects of the improved drugs using both biological and clinical symptoms will be based on those of a product that is already on the market.

Summary of discussions on above presentations of resource persons

The first presentation was on the processing technologies and good manufacturing practices for the production of plant-based medicinal drugs. Delegates welcomed the methods recommended in the context of appropriate technology with a few observations. delegates observed that extraction methods using resins should not be credited to China as such, since they are used elsewhere.

It s noted that resins are not only cation or anion retaining, there are some special resins. It was pointed out that there is a need to determine the best resin type to use according to situation. Delegates also enquired if there was a UNIDO developed universal extraction equipment in a similar context to the Polyvalent plant.

It was learnt that only one was produced for extraction of ostenoside. It was also noted that while in traditional practice plant and animal extracts are mixed, industrial processing on animal extracts is more complex.

Delegates also raised several comments on the quality control and marketing authorization of African traditional drugs. It was agreed that quality controls is important for validation of the drugs. It was clarified that UNIDO is concerned with validation of the preparation process of whatever traditional drug is used locally to standardize it while WHO is largely concerned with validation of the therapeutic drug itself. It was expressed that while validation is necessary, there should not be too much experimental wish done to convince medical circles. It was emphasised that while quality should be ensured, there is need to satisfy local supply before export considerations are made. Delegates maintained that traditional medicines have dosages that are usually less toxic than western products. The application of these dosages need to be simply improved.

Delegates also commented on the evaluation of the efficacy and safety of herbal medicines and development of new plant-based drugs. It was noted that while development of new drugs from crystallised pure compounds may divert pressure from the source plant, crystallisation is not always necessary.

It was argued that an extract should also be considered active not only crystallised forms. A UNIDO/WHO collaboration was commended in the context of a multidisciplinary demand in the development of new plant-based drugs.

OAU Scientific, Technical and Research Commission (OAU/STRC)

OAU has recognized Africa's problem in developing traditional medicine and hence has made contact with WHO to jointly find solution to the common problem. Out of this contact a programme was prepared which is in operation for the past few years. Included in the programme is an inventory of medicinal plants of the member states.

The representative outlined the training programme already being conducted at educational institutions starting first with the English speaking countries. He also outlined various assistance available for qualified students to attend educational institutions.

VIII. SUMMARIES OF COUNTRY REPORTS

Burkina-Faso

Pharmacological studies have been conducted. Some achievements include research and results on antibacterial, anti venereal, antidiabetic agents; propagation of medicinal plants; manufacture of capsules and tablets; and clinical studies continue.

Cameroon

There are four well-equipped laboratories which have put a number of products on the market which are reorganized internationally. However, there are problems of marketing and research.

Congo

The Congo traditional medicine service deals also with non material aspects.

Côte d'Ivoire

Through individual commitment a number of drugs has been produced.

Ethiopia

The Drug Research Department deals with traditional medicine research. The government has produced two policy documents to maximise national effort to develop traditional medicine drugs. Research effort is being organized.

Ghana

Has a Centre for Research and Traditional Medicine which trains herbalists, conducts standardization, formulation and clinical trials. An aboretum has been set up and the must frequently used plants have been classified.

Gabon

Nothing really concrete happening in the area of developing plant medicine. Initiatives are solely private and traditional healers need supports to acquire some of the strategies from experienced countries.

Guinea

A set up called Pharmaguinea was formed with the function of producing drugs which came out with three preparations which were promising but change of policy led to the closing down of this pharmaguinea giving way to private initiative and therefore approving to WHO and UNIDO for re-lunching of traditional medicine in Guinea.

Malawi

There is no plant based production of drugs. However, phytochemical analyses of some medicinal plants have been conducted at the University of Malawi. Currently, the National Herbarium and Botanic Gardens of Malawi has a project on ethnobotanical survey and conservation of medicinal plants.

Mali

Research in plant medicine has gone far where drugs have been produced ready for marketing. Government legislation also exists to regulate production of medicines. Problems however exist with the cultivation of the two plants used but with the co-operation of Burkina-Faso, have managed to establish farms. Quality control set up only required.

Mozambique

After several ethnobotanic studies, research and production efforts are being organized.

Nigeria

The efforts of the National institute for Pharmaceutical Research and Development (NIPRD) have yielded four drugs which are currently under clinical triads. In November 1996, NIPRD will host the West African Society for Pharmacology Conference and Regional Workshop on Cultivation and Conservation of Medicinal and Aromatic Plants (in collaboration with UNIDO). Details will be communicated to delegates later.

Senegal

Faculty of pharmacology, University of Dakar has developed a number of plant based drugs. There is no manufacturing done by the industries. The nongovernmental organisation funded project, studied the pharmacology, toxicology and chemical properties of five plant species.

Sierra Leone

Faculty of Pharmaceutical Science in collaboration with Chemistry Department, University of Sierra Leone conduct research on traditional medicine. There is manpower available to start manufacturing.

Togo

The Botanical Centre for Therapeutic Research has produced many drugs. There is need to prepare a national pharmacopoeia.

Uganda

There is government policy to produce herbal medicines of officious quality and to promote conservation and propagation of medicinal plants. There is emphasis on rigorous screening of efficacious herbs, according to the regulations of the National Drug Authority.

Zaïre

Computerized ethnobotanical information is available. The Pharmaceutical Department, University of Kinshasa has produced a number of drugs sold on the market. However, production has problems of quality control due to inadequate equipment.

Zimbabwe

Zimbabwe has an expanding on the on going programme on medicinal plant based drug production. Medicinal plant based products are currently being manufactured by Essential oil (PVT) Ltd. a number of private companies. The Research and Development in medicinal plant is being spearheaded by the Department of pharmacy at the University of Zimbabwe. The Departments also runs courses in Natural Medicine.

Associations dealing with medicinal plant products include the Zimbabwe Traditional Healers Associations, Natural Products Association of Zimbabwe, Plant Oil Producers Association and Essentials Oil Producers Association. These associations will be affiliated to the Southern African Federation of Herbs, Spices and Essential Oils whose headquarters will be in the Department of Pharmacy at the University of Zimbabwe.

Zimbabwe through the help of UNIDO, IDRC and private companies curried out four extensive market surveys since independence, all of which indicated that there is great economic potential in the industrial utilization of medicinal plants in Zimbabwe.

IX.. CONCLUSIONS

The Expert Group Meeting agreed on the conclusions set out below:

(1) Health Care in Africa depends primarily on the use of medicinal plants. Traditional practitioners collect appropriate plants, prepare herbal medicines and dispense to their patients. In some countries, small scale production of herbal medicines exist but requires significant GMP and quality control inputs. The need for the development of this Sub-sector particularly systematic documentation of medicinal plants, their cultivation, R & D, regulatory requirements, human resource development and facilities for the industrial scale production of plant based standardised, good quality medicines, is overwhelming.

(2) Most of the governments in the region have not accorded official recognition to traditional medicine. Thus, regulations guiding use of traditional medicines, and guidelines for registration of practitioners need to be appropriately determined. In this connection, "Guidelines for the Assessment of Herbal Medicines" and "Research Guidelines for Evaluation the Safety and Efficay of Herbal Medicines" prepared by WHO will be useful reference materials.

(3) Modalities and regulations for adequate compensation for the use of traditional knowledge are not available.

(4) Uncontrolled collection and use of valuable plants can lead to biodiversity conservation problems and even to extinction of some species.

(5) It is essential to quickly provide infrastructural facilities, trained human resources, information management and finance. This can be achieved by co-operation among developing countries and the support of developed countries, international organisations and industry.

(6) Women could play a more effective role in cultivation, harvesting, processing, R & D, production and marketing of herbal medicines.

X. RECOMMENDATIONS

Based on the above conclusions, the participants recommend the following steps at national, regional and international levels to optimise and improve the utilisation of herbal medicines in health care and to promote the production of standardised, good quality herbal medicines in adequate amounts.

A. National level

1. The Governments should establish committees comprising of experts from the sectors of Industry, Health, Agriculture, Trade and Research institutions to:

   (a) advise on the necessary guidelines and procedures for the registration of traditional practitioners and herbal medicines;

   (b) propose modalities and effective regulations to control the collection, , quality assurance, marketing and export of medicinal plants to minimise undue exploitation and to conserve biodiversity;

   (c) develop plans for the effective industrial utilization of medicinal plants including commonly used and endemic plant species.

2. Countries are urged to prepare and periodically update inventories (preferably computerised data bases) of all medicinal plants and other endemic and endangered species.

3. Research institutions should be established or strengthened for the development of all aspects of herbal medicines including:

   (a) improved agricultural practices;

   (b) collection, harvesting and post-harvest management;

   (c) efficacy and safety evaluation of selected herbal medicines;

   (d) standardization;

   (e) controlled clinical studies;

   (f) pilot scale processing facilities;

   (g) improved dosage forms;

   (h) quality assurance.

4. Research funds should be established for the purpose of R & D of herbal medicines and industrial utilisation of medicinal plants.

5. Greater participation of women in various areas such as cultivation, production, evaluation and marketing of medicinal plants should be encouraged.

6. The interaction between academic and technological institutes as well as the private sector should be encouraged.

7. Rational use of herbal medicines in the national health care delivery system and preparation of herbal formularies should be promoted.

8. Development of human resources necessary for various aspects of medicinal plant industry should be accorded the highest priority.

9. R & D institutions should be encouraged to develop suitable and viable packages for the industrial utilisation of medicinal plants

10. Ethical review boards should be established for animal and clinical studies.

11. Control systems should be adapted to improve yields and minimise energy consumption;

12. Solid waste products should be utilised for economic purposes e.g. fuel, fertiliser, paper and animal feeds.

B. Regional Level

1. A regional database and information centre should be established in order to provide the necessary information on all aspects of industrialisation of medicinal plants e.g. drug development, formulation technology, patent, marketing, clinical studies, side effects etc and to develop a regional information network using compatible software. OAU should act as the Nodal Agency for this purpose.

2. A regional R & D centre should be established which should spearhead development activities in pilot production of herbal medicines. The Centre should provide facilities for advanced training and sophisticated techniques for pre-clinical studies, standardization and process technology.

3. Coordinating committee should be formed at regional level to promote the following: education, organization of workshops, funding, registration, marketing, access to information, harmonisation of regulations and policies.

4. OAU initiated activities vis-a-vis training of technicians and provision of spare parts and reagents should be expanded.

5. OAU should declare a decade for the development of herbal medicines.

6. Formation of regional associations of academics, practitioners, technologists and entrepreneurs should be initiated.

C. International Level

1. Monographs on standardised herbal medicines already in the local markets should be prepared by OAU.

2. In view of the critical role played by UNIDO in establishing plants and technology transfer, it is necessary that this activity is continued at an accelerated pace, particular attention should be paid to the countries which have not received such assistance so far.

3. Since WHO has experience in pre-clinical and clinical evaluations of efficacy and safety of herbal medicines, it should organise workshop an different stages of preclinical and

clinical evaluation of herbal medicines and the minimum safety standards.

4. Utilisation of other available resources for South-South and South-North collaboration should be promoted for the development of industrial use of medicinal plants and human resources. In this regard, bilateral collaboration agreements, Third World Academy of Sciences, Non-Aligned Movement, Centre for Science and Technology and other NGOs should be actively explored.

5. WHO, UNIDO and other Agencies should facilitate the establishment of Regional R & D Centres, Access to international data bases, protection of intellectual property, human resource development, technology transfer, follow-up workshop and periodic symposia for the expansion of activities in this Sub-sector.

ANNEX 1

Discussion Papers:

1. Regional overview on the industrial utilization of medical plants for health care systems in Africa - Prof. M. Gundidza.

2. Processing Technologies and GMP for the production of plant-based medicines - Prof. Y. Chen.

3. Efficacy and safety evaluation of herbal medicines and development of new plant-based drugs - B.N. Dhawan.

4. Research, Development and Production of Plant-based medicaments in Africa: A case study in Rwanda - Prof. Luc Van Puyvelde.

5. UNIDO's technical cooperation activities in the area of medicinal plants - Special Technical Adviser, Chemical Industries Branch, Industrial Sectors and Environment Division.

6. WHO activities in the area of traditional medicine in Africa - Dr. M. Koumaré.

7. Quality control and marketing authorization of African traditional drugs - Dr. M. Koumaré.

ANNEX 2

PROGRAMME

Monday, 20 November 1995

08:00-08:30	Registration of participants
08:30-09:00	Opening statement by the Representative of the WHO Regional Director
09:10-09:20	Statement by the Representative of UNIDO - Senior Industrial Development Officer, Industrial Cooperation and Consultations Service, Investment and Technology Promotion Division
09.20-0930	Nomination of officers; Adoption of agenda and method of work
09:30-10:00	Coffee break
10:00-10:50	Presentation of UNIDO's technical cooperation activities in the area of medicinal plants - Special Technical Adviser, Chemical Industries Branch, Industrial Sectors and Environment Division
10:50-11:30	Research, Development and Production of Plant-based medicaments in Africa: A case study in Rwanda - Prof. Luc Van Puyvelde
11:30-12:00	Presentation of WHO activities in the area of traditional medicine in Africa - Dr. M Koumaré
12:00-12:30	Discussions on all presentations
12:30-13:30	Lunch Break
13:30-16:00	Presentation by participants of the experience of their respective countries
16:00-17:00	Discussions

Tuesday, 21 November 1995

08:15-09:00	Presentation and discussion on the processing technologies and good manufacturing practices for the production of plant-based medicinal drugs - Prof. Yingjie Chen
09:00-09:15	Coffee Break
09:15-10:15	Presentation and discussion of the evaluation of the efficacy and safety of herbal medicines and development of new plant-based drugs - Prof. B.N. Dhawan
10:15-11:30	Regional overview on the industrial utilization of medical plants for health care systems in Africa - Prof. M. Gundidza
11:30-12:30	Presentation and discussion on the quality control and marketing authorization of African traditional drugs - Dr. M. Koumaré
12:30-13:30	Lunch Break
13:30-15:30	OAU/SRTC paper and Country papers continued

15:30-16:00 Requests for technical assistance from UNIDO - Special Technical Adviser, Chemical Industries Branch, Industrial Sectors and Environment Division.

Wednesday, 22 November 1995

08:00-10:00 Group discussions

10:00-10:30 Coffee Break

10:30-12:30 Group discussions (continued)

12:30-13:30 Lunch Break

13:30-16:00 Plenary session: Consideration of the reports and recommendations of the working groups

Thursday, 23 November 1995

09.00-11:30 Finalization of the report and recommendations by the secretariat

12:30-14:00 Lunch Break

14:00-15:00 Closing session
Adoption of the draft conclusions and recommendations

ANNEX 3

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