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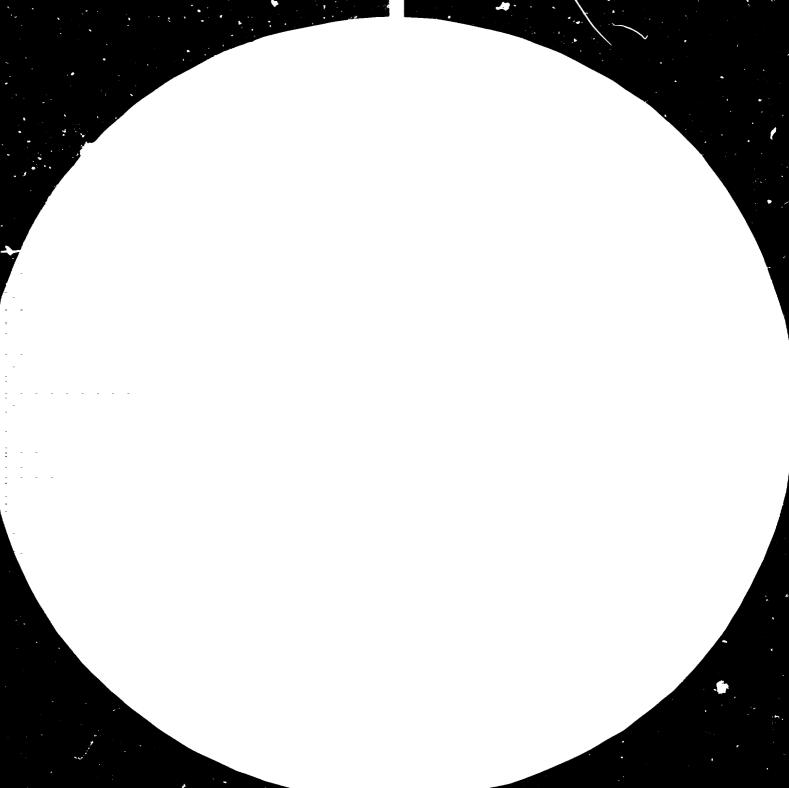
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UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

Workshop on the Pharmaceutical Industry (combined modern-traditional Pharmacy)

for Promoting Technical Co-operation among the Developing Countries

Beijing and Hanzhou, 1 - 14 November 1982

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TRADITIONAL PHARMACOPOEIAS REVISITED\* .

<u>A resumé of the goals and philosophies underlying</u> <u>UNIDO's programmes in the industrial utilization of</u> medicinal and aromatic plants in developing countries

prepared by

Pharmaceutical Industries Unit Chemical Industries Branch Division of Industrial Operations

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A resumé of the goals and philosopies underlying UNIDO's programmes in the industrial utilization of medicinal and aromatic plants in developing countries.

## I. Introduction

The story of man's life on earth is dominated by the symbiotic relationship with the plant Kingdom. It was from plants that primitive man derived materials for his food and drink, his clothing and shelter, and his health ,happiness, and general wellbeing. In the quest for drugs tc conquer disease man came across plants with healing properties, and doubtless some of them he first tried were toxic or had unpleasant reactions. However over the many millennia there has evolved in every culture and region of the globe groups of plants that are considered safe, efficacious, and are in use even today for curative purposes. Similarly, there has evolved also a further group of plants , aromatic by nature, from which are derived perfumery and flavour-giving substances which have a variety of uses in our industrialised world. Almost all drugs commonly used by man today, fall into the following categories:

I. Drugs Derived from Natural Sources

Animal , Vegetable and Mineral

II. Synthetic Drugs

Totally Synthetic
Partially Synthetic
Modified Plant Constituents

III. Drugs Obtained by Microbial Action

The Synthetic drugs are of comparatively recent origin the synthetic drug industry came about only after the massive developments in organic chemistry that followed World War II.

Drugs derived from natural sources have indeed dominated all but the comparatively infinitesimal part of time represented by four or five modern decades. There is therefore much relevance in the fact that, given the recent emergence of a large part of the globe with aspirations and hopes towards a better life, there should commence a trend towards re-examining the traditional cures of the past, which are to a very large extent derived from plants. This does not in any way represent a movement backwards, but it is very much a revisit to old tratitions to examine what the application of modern science and technology could come up with, from the treasures of the past.

#### II. Problems, Prospects and Practices in the Production of Plant-derived Pharmaceuticals

The problems facing developing countries in processing pharmaceuticals for use in their health-care systems are enormous and sometimes intractable. The foreign exchange resources of many countries do not permit the acquisition of even their basic needs in essential drugs. One major way in which this situation may be met is in the development of pharmaceuticals derived from plants

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used in the traditional systems of medicine. In almost all countries of the world where traditional systems of medicines are practiced, where the main therapeutic agents are derived from plants, the drugs are prepared directly from the plant material in one or other of the simplest of methods eg.:

- Extraction with cold or hot water
- Crushing and compressing materials which are generally succulent.
- Pulverising and admixture with oils

Several concerns are associated with such simple methodology, such as:

-	Has the plant species been correctly authenticated?
-	Is the method of preparation used, consistent with the prescribed one?
-	Are the dosages employed in accordance with prescription?
	Is the raw material used of approved quality?

Standardised procedures and techniques in the preparation of such extracts would be a first step in the utilization of plant-derived pharmaceuticals in developing countries.

In order to ensure the wide acceptance of extracts by health authorities in both developing and developed countries it would be necessary to ensure the following:

- Authenticated plant material of uniform quality.
- Strict conformity to prescribed/predetermined methods of extraction
- Rigid control of quality during all stages of production and in the final products.

During the past ten years there have been many instances where extracts of drugs produced from plants used in the traditional pharmacopoeias of developing countries have been processed by modern technological means  $\frac{2}{}$ , in the light of the above requirements. Many such drugs have been successfully introduced into use in developed countries even in Europe (Table 1).

## TABLE 1

Some extracts from plants used in the traditional pharmacopoeias of the world that are now available as modern , industrially processed pharmaceutical preparations

	EXTRACT OF	USE IN TREATMENT
1.	P <u>rurius africana</u> (Hook)Kalk.	Adenoma of the prostrate because of the anti-testosterone activity of some of its constituents.
2.	<u>Centella asiatica</u>	Syndromes calling for a non- steroidal anti-inflammatory healing agent.
3.	Siliabum marıanum	Normalisation of liver dysfuntions
4.	V <u>aleriana wallichi</u>	Non sedative tranquillisation
5.	Panax ginseng (C.A.Meyer)	Anti-stress agent
6.	Anarcardium occidentale	Anti-amoebic agent Anti-hypertensive agent
7.	Simarouba glanca	
8.	Rhamnus purstriana D.C.	Laxative action
	Rhamnus frangula L	Laxative action
9.	Passiflora incarnata L	
10.	Silybum marianum (L.)	
11.	Vaccinium myrtillus L.	In opthalmology for treatment of hemeralopia, capillary diseases, circulatory disorders
12.	Ruscus aculeatus L	Anti-inflammatory drug Haemorrhoids, Varicose veins.

In addition there are many new extracts which on account of their long standing "clinical" use in traditional pharmacopoeias, and in the light of the results of recent researches utilising established scientific normes, are receiving close attention.

Some such examples are the following:

Mormodica charantia	Treatment of Diabetes
Commifora mukul	Found useful in reducing
Anethium graveolens	Atherosclerotic syndrome

There are also many others with promising clinical effects which can be industrially prepared into dosage forms for the use of developing as well as developed countries (TABLE II)

## TABLE II

<u>Plant</u> species with promising clinical effects, (currently used in traditional medical therapy) which warrant industrial processing.

Indication	Plant source	
Parasitic Diseases		
(a) TAPEWORM	Cucurbita maxima Duch.(seeds) Cucurbita pepol. (seeds) Punica granatum L (fresh bark)	
<pre>(b) SCHISTOSOMIASIS   (Bilharzioses)</pre>	Securinega virosaBaill.(leaves,twigs)Diatium dinklageiHarms.(leaves)Pargularia extensaN.E.Br.(latex)Cnestis ferrugineaDC (roots)Combretum glutinosumPerr. (fruits)Tylostemon maniiStapf. (fruits)Borreiria verticillata G.F.Mey(whole plant)Zizyphus mucronataWilld.(roots)Hibiscus furcatus Roxb.(leafy stems)Ageratum conyzoidesL. (Aerial parts)Cochlospermum tinctoriumA.Rich.(rhyzomes)	
(c) OTHER ANTI-		
HEIMINTIC AGENTS	Securidaca longipendanculata(roots)Ploygala senega(roots)Phytolacca dodecandra(roots)Chenopodium ambrosoides (aerial parts)Pooygonum senegalensis (leaves)	
(d) ANTI-AMOEBIC AGENTS	Hollarhena floribunda (seed or roots) Anarcardium occidentale (kernal) Euphorbia hirta (whole plant) Simaruba glanca (bark)	
(e) ANTI-MALARIAL AGENTS	Mitragyna spp. Corynanthe pachycoras Nauclea latifolia Morinda citrifolia Crossopterix febrifuga Khaya senegalensis Guiera senegalensis Combretum micranthum	

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TABLE II contd.

Indication		Plant source
Farasitic Diseases		
(f)	ANTI-MICROBIAL AGENTS	Several species of Flacourtaceae Centella asiatica
(g)	ANTI-LEUCODERMIC AGENTS	Heracleum spp.

These plants (Table II) are only some examples where the technology for the production of extracts or active ingredients is already known invariably to commercial drug firms in the industrialised countries. In several instances there are patents covering the extraction process and although the plant itself is grown in a developing region its utilization for therepeutic preparations could be legally hindered.

Accordingly, there is no question but that in modern pharmaceutical policy, particularly in developing countries, the industrial production of drugs from plants must for economic as well as reasons of health - care practice, receive high priority, in terms of Research and Development, and the technology must thereby be evolved for the processing of these plants into drug forms. Much of the R and D efforts during the past few decades, where plant drugs of reputed efficacy are concerned have been carried out in the industrialised countries, on plant material gathered from developing countries and so has not benefitted the country in which the plant was originally located.

Invariably, the following sequence has been followed:

- Verification of Ethnomedical Information
- Collection of Plant-Material
- Chemical Studies
- Studies on Bioactivity / Toxicity etc.
- Isolation of Active Ingredients
- Synthesis of appropriate analogues
- Marketing of synthetically produced compounds.

Examples of this type of activity range form the production of Quinine in Europe from Cinchona bark produced in Africa and South America to the recent US National Cancer Institute screening of African plants for anti-tumour agents. The plant material is more often than not exported to the industrialised country in the crude form. This sequence, as fully realised by UNIDO  $\frac{1}{2}$ , has not served in any way to the benefit of the developing countries. Generally, biologically interesting compounds have been isolated and their chemical structures have been elucidated . Sometimes their pharmacological activities have also been systematically studied, and where promising results have been forthcoming in a very small percentage of compounds, the natural products themselves or analogues have been synthetically prepared. Such synthetic products after rigorous evaluation are marketed by drug firms, and the poor developing countries pay dearly for their acquisition. The question clearly begs itself: Why cannot the original plant be systematically cultivated, and a drug from it processed in the country or countries in which it is grown? Must the discovery of new drugs from plants invariably end, by making the plant-drug sacrificial to the synthetic process? Clearly, an alternative approach to drug development ought to be considered which would directly and speedily benefit the developing countries.

There is a powerful case for a methodology where the ethnomedical preparations are simulated to that they are equally effective and can be produced using modern technologies. UNIDO programmes have therefore been directly towards this end.

There is also yet another question to be considered here. In the traditional systems of medicine, plant preparations are used where more often than not several plant species are included, as a single prescription for a given disease. It is contended that in the case of such "polypres-criptions" the individual effect of the plant species that is specific for a particular disease is rendered more effective and would have less harmful side effects than when it is used by itself. Therefore to test the plant individually would render the results clearly of limited value. There are instances  $\frac{4}{}$  where it has been

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proven that the extract of a whole plant made according to ethnomedical prescription is more effective and less toxic than the individual constituent in it. Hence much of the work done hitherto on the evaluation of plant medicines suffers in the light of this consideration .

It is therefore necessary - and UNIDO programmes have taken this into account- to reconsider the approaches to drug development from plants, because the expense for instance, of the isolation of a pure constituent does not make sense if the specificity displayed by the extract is lost, and is therefore not justified on therapeutic grounds. Furthermore, techniques are now available  $\frac{5}{6}$  for the manufacture of both solid and liquid pharmaceutical preparations utilising plant-extracts without jeopardising their efficacy, and indeed enhancing their stability.

The general tendency to isolate pure compounds from plants, is dictated by the following considerations:

- the possible discovery of new structural types with interesting biological activities.
- the facility with which pure compounds can be pharmacologically assessed, and standardised dosage forms prepared.
- the stringent requirements of Public Health Authorities in terms of toxicology tests and standardisation.

While the first two of these are justified on scientific grounds, and also in enabling methods to be devised for the quality assessment of products based on total extracts as well, there must arise some reservations regarding the third. The World Health Organisation, and many national drug regulatory authorities demand the same requirements for toxicological and teratogenic assessment of drugs produced from plants, as for synthetically produced durgs. While great precautionary measures are justified in the case of drugs from the synthetic process, the same cannot hold for preparations derived from plants which people have been using for generations. Surely, more realistic criteria for them must be evolved. For example conducting animal experiments on preparations of plants such as <u>Coriandrum sativum</u>, <u>Centella asiatica</u>, or <u>Momordica charantia</u> and the like, which are being routinely used by people (and have been for several millenia) as drugs and even as food

It is hardly surprising that there are many who yet believe that strict quality control of multiple constituent plant extracts is not within the realm of possibility. Admittedly such quality control methods are not as simple as when only pure compounds are involved. But they are possible and recent publications document a host of such methods  $\frac{5-10}{}$ . For example modern analytical methods such as IR,UV, GLC,HPLC are most effectively used in the quality control of drugs derived from plant extracts.

# III. Industrial processing to serve the needs of developing countries

There are several approaches  $\frac{11-14}{}$  to the utilization of plants for the industrial production of pharmaceuticals. However, an approach characterised by service to developing countries would be one which is based securely on the systematic cultivation of the plant species in developing countries and one which seeks to manufacture such pharmaceutical formulations that may be produced within the developing countries themselves.

Considering traditional as well as current practices, the utilization of medicinal plants today may take one or other of the following forms:

1			
l	A.	DIRECT UCE:	Use of Fresh or Dried Material
	В.	EXTRACTION:	Preparation of Decoctions , Tisanes, Tinctures, Galenicals, even Pills and Tablets from Total Extracts.
r	с.	ISOLATION OF CONSTITUENTS:	As raw material for the Extraction and Isolation of pure constituents or Isolates for therapeutic use.
	D.	SYNTHETIC INTERMEDIATES	: As raw materials for the isolation of Inter- mediates for the Synthetic Production of Drugs.

The direct use of plant material, is a feature of the systems of traditional medicine, not only in the developing areas of the world, but also in Europe where nowadays one finds a considerable resurgence of faith in plant-derived medicines. The production of extracts, tinctures, tisanes, galenicals, and other forms is also common in many countries, albeit in varying degrees of sophistication.

CHINA, for instance has pioneered the utilization of the technology developed by modern science in the preparation of plant-derived medicines and in the integration of modern technologies with ethnomedical

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knowledge and its application  $\frac{14}{}$ .

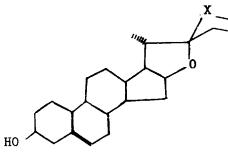
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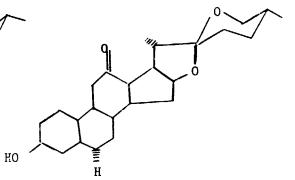
The isolation of constituents, their purification and preparation into drug forms, coupled with their biological evaluation on animal species followed by dinical trials of varying degrees of exposure to humans, has been the preferred pathway of drug development followed in the industrialised world. This methodology not only requires high-cost, sophisticated technology -not available in most developing countries- but involves animal experiments, for toxicology and teratology with enormous outlays in funds. The time-frame from availability if pure compounds, to development of drug forms with licence for clinical usage, is of the order of 6 to 15 years. Foor developing nations which most require the drugs can neither afford the time nor the funds for such exercises.

The fourth category of usage namely the production of intermediates for the synthesis of drugs can however be of some use to developing countries.Two cases will exemplify this:

The first is the preparation from plants of intermedicates in the production of Corticosteroids  $\frac{15}{}$ . These were originally obtained by extraction from animal sources and later from partial synthesis from Cholesterol.

In the 1940's R.E. Marker working in Mexico, found that some Steroidal sapogenins obtained irom plants, in particular Diosgenin from <u>Discorea</u> spp. could be utilised for the preparation of certain corticosteroids, like cortisone and prednisone which were widely useful drugs.Development of synthetic methods by C.Djerassi also enabled the production of a practical oral contraceptive utilising Diosgenin-type compounds and therby the international market for such steroidal intermediates increased considerably.





HECOGENIN

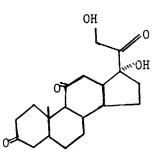
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X = -O-: DIOSGENIN X = -NH- SOLASODINE

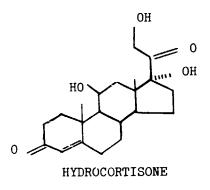


Several stages.

CORTICOSTEROIDS



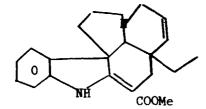
CORTISONE



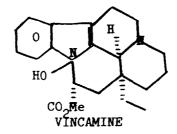
PREDNISONE

As a result, various species of Dioscorea such as <u>D.deltoidea</u> Wall and <u>D.floribunda</u> are now being cultivated in countries such as Mexico and India for production of Diosgenin.Similarly, the steroidal alkaloids like Solasodine, the nitrogen analogue of Diosgenin, are a group of compounds present in the <u>Solanum</u> spp.which are an attractive source of steroids for drugs and which can be grown in many developing countries.

Another example is Tabersonine, a principal constituent of



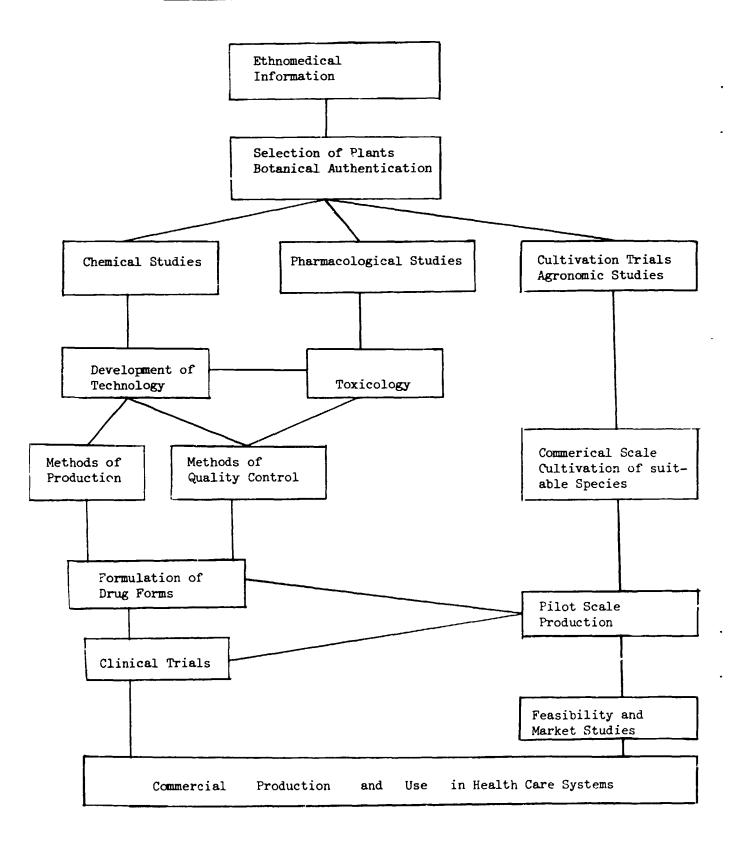
TABERSONINE



the African species <u>Voacanga africana</u> and <u>Voacanga thoursii</u>. Tabersonine can be synthetically converted to the oncolytic drug Vincamine. Vincamine although the most biologically significant alkaloid of <u>Vinca minor</u> is present in only small amounts in the <u>Vinca spp</u>. Its production from Tabersonine is acommercially viable proposition and there are several patents covering its synthetic conversion.

The production of Tabersonine from <u>Voacanga spp</u>. is an attractive proposition for many African countries, although its conversion synthetically to Vincamine requires fairly sophisticated synthetic capability.

It must be recognised therefore that there are many considerations in planning the developing of a pharmaceutical industry based on medicinal plants in a developing country. The stages needed are outlined in the <u>Scheme A</u>. From the developing country view point it is most important that production activity is based on the systematic and cropwise cultivation of selected plant species. Dependence on the spontaneous flora can lead to dangers such as inconsistencies in the supply of raw material for processing and even in the extinction of a species. Accordingly, agronomic studies must be initiated following the identification, authentication and selection of plant species for utilization. Chemical and Pharmacological studies logically precede the choice and acquisition of necessary technologies, as well as the development of suitable methods of quality assessment of raw material and finished products. The data on the chemical composition together with the pharmacological responses are necessary in the formulation of suitable dosage forms.Pilot scale production trials should precede the feasibility studies as well as cilinical trials for which reasonable quantities of standardised material should be made available. Commercial production can commence only after quality, efficacy and acceptability have been assessed and a continuing availability of raw material and suitable technology is assured. SCHEME A



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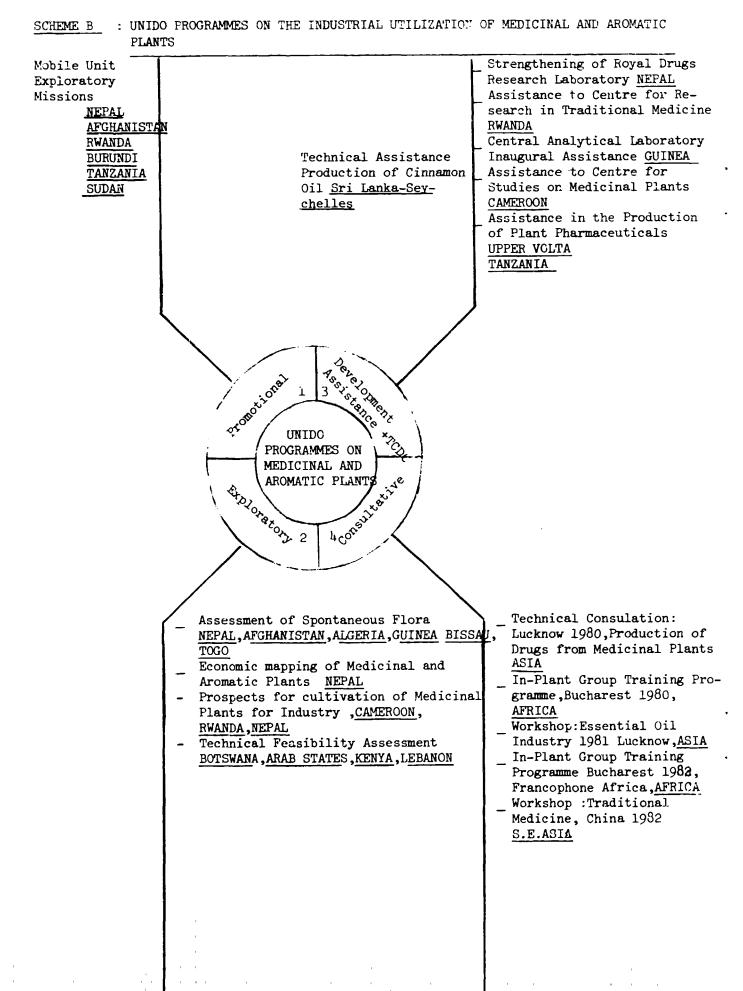
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## IV. An outline of the UNIDO programmes in the industrial utilization of medicinal and aromatic plants

UNIDO's programmes in the area of medicinal and aromatic plants  $\frac{1}{}$ in the past five years and more have tended to accent firstly the aspect of industrial utilization in keeping with UNIDO's mandate: " to promote and accelerate the industrialisation of the developing countries". Secondly, all UNIDO programmes have been developed, mindful of the problems and concerns from the developing countries standpoint that have been discussed previously. Broadly looked at these programmes could be devided into the following four categories :

- I. Promoti Gal Programmes
- II. Exploratory Programmes
- III. Development Assistance Programmes
- IV. Consultative Programmes

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#### 1. Fromotional Programmes

The main promotional programme took the form of a unique exploratory mission by a Mobile Unit organised by UNIDO with the collaboration of the Joint UNIDO-Romania Centre Bucharest.

This programme was confined to the Least Developed Countries of Asia and Africa. The Mobile Unit itself consisted of two four-wheel-drive vehicles so outfitted that they carried instrumentation and laboratory facilities to enable the five-man "crew" of Romanian scientists and technologists, to carry out basic laboratory screening-tests, and semi-pilot scale operations on plant material. The mobile unit first visited Afghanistan, Nepal spending a total of five months from departure and return to Bucharest.Their African phase included visits to Botswana, Burundi, Rwanda Sudan and Tanzania . In the course of an arduous and rewarding project the team was able to accomplish much in the way of

- gathering data on the spontaneous flora of each country visited
- listing and authenticating important species of medicinal plants growing in each country
- demonstrating methodologies of :field botany; phytochemical screening and pilot scale methods of extraction and distillation
- establishing liaison with interested institutions in each country visited and with local scientific and technological personnel.

The success of this exploratory mission and the interest it generated may be gauged by the fact that UNIDO has already been able to initiate full fledged technical assistance programmes in Nepal, Rwanda and Botswana on the production of Pharmaceuticals from Plants. In the next two years projects in Tanzania and Sudan will als commence. The Mobile Unit Mission which cost around US\$ 80.000 could be considered a success in these terms alone.

#### 2. Exploratory Programmes

The exploratory programmes of UNIDO are considered a necessary prerequisite for the initiation of long-term technical assistance programmes. The production of pharmaceutical: from plants on an industrial or semi-commercial scale becomes a viable proposition only if the rawmaterial for processing is available continously and in the required quantities. For this purpose, it is necessary to understand that total dependence on the spontaneous flora will eventually be detrimental to industrial prospects, as well as environment. Placing the plant species selected for processing on a crop basis, is thus a prime requirement. Accordingly, UNIDO's exploratory programmes have taken the following forms:

- (a) Economic Mapping of the Spontaneous Flora
- (b) General Assessment of the Plant Resources forest flora as well as cultivated for utilization in pharmaceutical production

The method of economic mapping devised by the Romanian scientist Mr.Ovidou Bojor  $\frac{16}{}$  seeks to obtain an idea of the number of plant species that could be profitably utilised and their relative abundance in a given geographic region. This method was most successfully used in making an assessment,with industrial processing in view, of the spontaneous flora of Nepal and Afghanistan. The Technical Assisstance Programme in Nepal in particular will take into account the results of economic mapping for both utilisation of forest flora as well as selection of plant species for cultivation on a crop basis, for industrial processing into pharmaceuticals.

Other assessment programmes of a general nature have preceeded the assistance projects in Rwanda, Cameroon, Guinea etc. Several other such programmes designed to qualitatively assess the flora for suitability for the purpose of initiating pharmaceutical production are now underway.

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#### 3. Technical Assistance Programmes

UNIDO'S Technical Assistance Programmes in this area involve the transfer of technology on the production of pharmaceuticals from medicinal and aromatic plants to the country concerned. This means the provisions of technology at one or more points in the series of operations represented in <u>Scheme A.</u> UNIDO has in the past provided several countries in Asia, Africa and Latin America and the Caribbean with assistance in:

- the assessment of the plant resource potential
- expertise in cultivation technology for industrial processing
- processing technology
- analysis and quality control methodology
- marketing and management of production

The projects in Nepal and Rwanda are examples where UNIDO is engaged in strengthening the resources, and capacity of the local institutions the Royal Drugs Research Laboratory, Kathmandu, and the Centre Universitaire de Recherche sur la Pharmacopie et la Médecine de Butare, Rwanda engaged in R and D activities.UNIDO provides the needed experts , assists in the selection, evaluation, and procurement of equipment for production as well as the means for analytical quality control.UNIDO's experts work in collaboration with national counterparts and the programme is a jointly executed, concerted effort to develop the industry within each country. Several other smaller UNIDO projects have been or are now being executed where UNIDO assistance has helped in developing Agronomic expertise, Analytical facilities, Researach and training facilities, towards the ultimate requirement of utilising the plant resources for pharmacological production. These include projects in the Cameroon, Guinea, Upper Volta, and Botswana.Like projects are now being developed by UNIDO in several other countries, of Asia, Africa and Latin America as well and hopefully will materialise into technical programmes reaching the execution stage in the near future.

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4. Consultative Programmes

Of recent UNIDO programmes in this category the main events have been the following:

- (a) A Technical onsultation on the Production of Drugs from
   Medicinal Plants in Developing Countries (Lucknow, India 1 3)
- (b) In-Plant Group Training Programme in the Field of Medicinal Plants : Anglophone Countries (Bucharest, 1980)
- (c) Workshop on the Essential Oil Industry (Lucknow, India, 1981)
- (d) In-Plant Group Training Programme on the Production of Pharmaceuticalsfrom Medicinal Plants:Francophone African Countries (Bucharest, 1982)
- (e) The current "Workshop on Pharmaceutical Industry(combined modern-traditional pharmacy) for promoting technical co-operation among developing countries " in China

One of the crucial needs in developing countries for the purpose of inaugurating projects on Medicinal and Aromatic Plants would be the building-up of an indigenous scientific and technological competence, within this area.

The multidisciplinary requirements of such a competence stretches accross a wide spectrum of subject areas, and involves levels of activity from that of the farmer who cultivates the crop to the highly skilled professional scientist. The successful interaction of the different skills and activities generates the infra-structural requirements for the industry. The rationale for UNIDO's consultation programmes is the building up of the indigenous competence and from reactions of many developing countries it may be concluded that the UNIDO programmes have indeed been more than fulfilling the prescribed function. Training of personnel is a most important aspect of the transfer of technology . In the context of UNIDO's programmes there are many constraints such as the dearth , in several countries of suitable personnel capable of undertaking training, and the non-availability of

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tailor-made training schemes for the activities concerned. However, over the years UNIDO has contrived to foremost in view the aspect of building national capabilities wherever UNIDO projects are being executed.

In conclusion, it will surely be seen, that though there is displayed interest nowadays in medicinal plants and their possibilities, to offer an inexpensive methodology for providing some useful drugs for the world's most needy, there still has to be developed a concerted global effort towards that end.Such an effort will need, long-term planning by all UN and other agencies interested in the subject, and more especially, the long-term availability of funds.UNIDO's efforts so far would therefore hopefully serve as a nucleus towards a future global effort in assisting the developing world build a pharmaceutical industry based on indigenous raw materials, and with maximum benefit to a greater part of the world.

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