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REGION OF LATIN AMERICA

Technical report: Review paper*

Prepared for the Governments of Region of Latin America
by the United Nations Industrial Development Organization

Based on the work of
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* This document has not been edited.

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ABSTRACT²

INDUSTRIAL UTILIZATION OF MEDICINAL PLANTS IN LATIN AMERICA

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Latin America consumes only a small percentage (4.9%) of the total world consumption of drugs, although it has about 10% of the world's population. Due to the limited coverage by health services and the lack of access of a significant part of the population to pharmaceuticals, plant based traditional medicines still play a vital role in the health care of the majority of the people in Latin America. Even in developed countries many plant based drugs are still used today and the trend is increasing. The biological diversity of the Latin American vegetation, especially the rich tropical flora is a potential source of drugs, which has yet to be fully explored.

Latin America exports many crude drugs mainly in the dried form and, to some limited extent, as simple extracts and even pure drug entities like pilocarpine and rutin. These plants are mainly gathered from wild sources, a practice that may endanger the species. Only a few countries in the region have large scale cultivation programs for a

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selected number of medicinal plants.

The use of finished pharmaceutical products in Latin America for 1990 was about US \$8.5 billions; however, the participation of industrialized medicinal plants in this market is insignificant due to the virtual inexistence of a Latin American industry based on plants. Local industries only prepare simple plant extracts or repack dried plant material (individual plant or mixtures) in suitable dosage forms. Industry infrastructure is poor and there is a dearth of qualified personnel in different aspects of pharmaceutical technology. The main problems that have hindered the development of this industry in Latin America are: lack of the knowledge about socioeconomic and medical benefits, lack of information about unitarian processes and manufacturing technology, reluctance of medical doctors in the prescription of phytopharmaceuticals, inadequate quality control methods, unpatentability of herbal medicine, unreliable supply of medicinal plants both in quality and quantity, lack of knowledge about the world market trends; and above all, the absence of clear national policies in the use of plant-based medicine in health care, which is translated in a lack of a legal framework for the registration of phytopharmaceuticals and an inadequate support of research and development in the critical areas of agrotechnology, therapeutic validation and the formation of human resources.

This paper will give an overview of the present situation of the medicinal plant industry in Latin America. It will state the needs and propose strategies and recommendations to stimulate industrialization of medicinal plants and their use in health

care in the Region. It seems obvious, due to the present socioeconomic situation, that efforts to industrialize plants should be concentrated on standardized preparations with a minimum added value, since the cost of production of phytopharmaceuticals with modern technology to manufacture sophisticated finished products will be very high and out of reach for most of the population of the region who need them.

Specific recommendations regarding medicinal plants which can be industrialized, priority research areas in agrotechnology, international commerce, natural products chemistry, pharmacology, preclinical and clinical studies, quality control and standardization, legal issues about the registration of phytopharmaceuticals and international technical cooperation and the role of international cooperation agencies will also be discussed. Results of a survey on the present status of the plant - based pharmaceutical industry in Latin American countries and personal on site visits and interviews with academic, industrial and public sectors will also be included.

INTRODUCTION

The United Nations Industrial Development Organization (UNIDO) in collaboration with the National Commission for the Utilization of Medicinal Plants of Guatemala (CONAPLAMED) convened an Experts' Group Meeting on the Industrial Utilization of Medicinal Plants in Panajachel, Guatemala during the period 11 to 17 July 1993. This is the first time that the UNIDO organized a meeting on this topic in the Latin American and Caribbean region. This meeting was organized with the objective of disseminating the results of UNIDO/US/GUA/84/282 project on the Utilization of Medicinal and Aromatic Plants for a plant-based Pharmaceutical industry in Guatemala and to recommend ways and means to promote active international cooperation among developing countries.

1. PHARMACEUTICAL MARKET

1.1. Participation of the Region

The world consumption of drugs in 1990 amounted to approximately US \$173 billion. The consumption in Latin America was only 8.5 billion, or slightly less than 5% of the world market. In 1980, the global consumption was US \$80 billion, while Latin America spent \$6.4 billion, or less than 8%. The figures from the last fifteen years indicate that the consumption of drugs in developing countries, including Latin America, has been decreasing in relation to the world consumption. This decrease has been further accelerated by the deteriorating economies of these countries. For example, in Brazil, the consumption of drugs, as percentage of its gross national product, (G.N.P.) decreased from 0.9% to 0.7% between 1975 and 1990 and the consumption per capita from US \$12.5 to US \$10.5 (in dollar of 1980) during the same period. While the consumption of drugs as a percentage of G.N.P. in developed countries increased from 1975 to 1990 from 0.65% to 0.95%, it decreased from 0.79 to 0.67% in the developing countries (Gerez, 1993). The differences in the consumption of drugs per capita in developed and developing countries are also very significant. While in Japan, the per capita consumption was US \$256 and in the United States of America US \$182, in Latin America this figure was only approximately US \$21.00. These

vary among different countries of the region (Argentina \$65, Brasil \$17, Bolivia \$6) and among different regions of the same country, as is the case in Brasil.

In spite of a low per capita consumption in Latin America, as compared with that of the developing countries, it is estimated that this represents a high percentage of the total health care cost (from 25 to 50%), while in the developed countries this percentage is considerably lower.

The obvious differences in purchasing powers of the population in Latin America, a low per capita consumption and a lack of resources in the public sector for the acquisition and distribution of drugs to the general population are some of the causes that make it difficult for the majority of the population to have access to drugs. The percentages vary among different countries of the region, but it is not unreasonable to estimate that 50% of the population of Latin America does not have access to drugs and a majority of these people use one or another form of medicinal plants for their health care.

The balance of payment of Latin America in drugs is significantly deficient. The bigger countries of the region like Argentina, Brazil and Mexico import approximately 10% of their requirements of finished

pharmaceutical products, while those of Central America import approximately 80%, and others. Like Chile, Peru, Venezuela and Bolivia import around 25 to 50%. The availability of raw materials and auxiliary products in the region for the production of drugs is very scarce and it is estimated that 75% of this need has to be met by importation. With respect to the finished products, the industry with national capital supplies 50% of the need in Chile and Argentina, 30% in Mexico and Uruguay; 20% in Venezuela, Brazil, Peru, and Colombia and only 10% in countries like Ecuador, Costa Rica and Panama. This means that a major part of the 8.5 billion dollar pharmaceutical market is supplied by companies with foreign capital.

The weak economic situation of the majority of the Latin American countries, the control of the market by the international companies and the patent protection laws imposed upon the countries of the region, among other factors, predict that in the future, access to drugs by the population in Latin America will worsen and unless adequate measures are taken, the companies with foreign capital will keep on dominating even more the pharmaceutical market and thus affecting the purchasing power and the economy of these countries.

1.2. Market of Medicinal Plants

It appears logical to think that poor access of the population to drugs, increased control of the market by transnational companies a continually decreasing participation of the public sector in the supply of drugs, should stimulate the use of cultivable medicinal plants in the region with the objectives of improving the health coverage of the population and decreasing the deficit in the balance of payment.

Use of medicinal plants as drugs is widespread in an important part of the Latin American population and in some countries this may amount to about 70%. In the industrialized countries, the market of drugs, based exclusively on plants, is important and the tendency is towards even a higher market. Moreover, plants are important sources of raw materials for the pharmaceutical industry.

As indicated earlier, the world market of finished pharmaceuticals was around US \$ 173 billion in 1990. Of this, a 25% contain today at least one compound of natural origin. If 5% of the compounds can be synthesized economically, it is reasonable to estimate that a 20% of modern drug products contain compounds which are extracted from the plants or are based on plant extracts. Therefore, it can be assumed that the world market of finished

pharmaceuticals of plant origin is approximately US \$35 billion annually. At the same time, many countries, whether developed or not make a wide-spread use of medicinal plants for the health care systems. For example, in Japan, the Ministry of Health and Welfare approved for their use 210 prescriptions based on Chinese traditional medicine. The Japanese Pharmacopoeia includes 164 crude drugs of plant origin and approximately 60 of them, like licorice, rhubarb angelica, and ephedra are used frequently. The value of these products of Chinese origin represented US \$32.2 millions in 1984, i.e. 12 to 13% of the market of non-prescription drugs.³

In China the traditional medicine is an integral part of the formal health system and it is utilized in 40% of the cases of primary health care. India recognizes officially the traditional medicine based on plants. The consumption of phytomedicinals in Europe is also significant (US \$3 billion in 1992) and many products are prescribed by the physicians, especially in Germany. The European Pharmacopoeia has monographs on some 40 medicinal plants.

In modern medicine, 121 chemical entities of plant origin are used today. Plants as a source of therapeutic agents thus continue to contribute towards the programs of health care and to the economies of both developing

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IMS Market letter 27 October 1986, p.25

and industrialized countries. Medicinal plants are often used in practically all countries of the world as raw materials, in the form of extracts, in semipurified form or as semisynthetic or chemically pure substances. In the majority of the world population that has no access to the modern drugs, the importance of medicinal plants and their use, in different levels of industrialization, is ever increasing. It is estimated that for the year 2020, the world population would have reached 7.5 billion. Of this total, 75% of the people will live in developing countries, which consume today less than 15% of the world pharmaceutical market. Thus, this population will have to depend in the future even more on the use of medicinal plants.

The aforementioned has stimulated the World Health Organization (WHO) to recognize, through Resolution WHA 31.53, the importance of medicinal plants in the health care called attention of the member states to utilize a comprehensive approach on the topic of medicinal plants. This was to include:

- "a. an inventory and therapeutic classification, periodically updated, of medicinal plants used in different countries;
- b. scientific criteria and methods for assessing the safety of medicinal plant products and their efficacy in the treatment of specific conditions and diseases;

- c. international standards and specifications for identity, purity, strength and manufacturing practices;
- d. methods for safe and effective use of medicinal plant products by various levels of health workers;
- e. dissemination of such information among Member States;
- f. designation of research and training centres for the study of medicinal plants."

In May 1987, the Fortieth World Health Assembly (Resolution WHA40.33) reaffirmed the main points of the earlier resolutions and the related recommendations made, in 1979, by the Alma-Ata Conference. This resolution provides a mandate for future action in this field.

Member States were urged to take, among others, the following actions:

- "a. to initiate comprehensive programmes for the identification, evaluation, preparation, cultivation and conservation of medicinal plants used in traditional medicine;
- b. to ensure quality control of drugs derived from traditional plant remedies by using modern techniques and applying suitable standards and good manufacturing practices."

The foreseeable increase in the use of medicinal plants in health care of the people of this region and the increased interest of developing countries in plant-derived drugs indicate that now is an appropriate time to stimulate the cultivation and export of indigenous and domesticated medicinal plants.

The complete world statistics on the commerce of medicinal plants and plant-derived pharmaceuticals are not readily available. These are difficult to obtain. However, the national commercial figures of the developing countries allow us to have a vision of global world commerce of most important plant-derived pharmaceuticals, as well as of the present trends in commerce. According to the principal trade center of medicinal plants in Hamburg, it is estimated that around 400 botanical products are important in international commerce. These botanical products are sources of plant extracts for different food, pharmaceutical and perfumes and cosmetic industries.

The United States of America and the European countries are the major importers of botanical products. These crude botanical products accounted for an import value of US \$750 million annually in the United States. According to a recent report⁴, the annual production of herbal

⁴ Akerele, O., Stott G. and Lu, W. (eds). The role of traditional medicine in primary health care in China. The American Journal of Chinese Medicine, Supplement No 1, 1987.

remedies in China was valued at US \$751 million and the country wide sales of crude plant drugs US at \$1.4 billion⁵. The Asian countries like India, China, Thailand, Indonesia etc. are the major exporters.

It is difficult to estimate Latin American exports of plants and their derivatives. Countries like Brasil, whose export value of only pilocarpine and rutin was approximately US \$ 16 million in 1985, imported many plants such as ginseng, boldo, chamomile, oregano, rhubarb, cascara sagrada, arnica, licorice, senega, valerian, mints, senna, aloe, opio, digitalis, belladonna, Ruta chelapensis and Rosmarinus officinales, some of which can be cultivated easily.

Based on the personal interviews through site visits and on the information gathered from the survey of the region through mail, it can be said that the Latin American countries do have a clear interest in the exportation of cultivated medicinal plants as a source of income for their weak economies and to improve local supply. In order to achieve this successfully, the countries will need to develop an appropriate agrotechnological base, will need to become aware of international market, and will need financial and technical support of national institutions and international organizations.

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Li Chaojin. Management of Chinese traditional drugs. The American Journal of Chinese Medicine. Supplement Nº 1, 1987.

1.3. Research

The medical potential of plant species in the region is very important. It has been estimated that there are approximately 500 000 plant species in the world⁶, 60-70% of which are found in Latin America, specially in the tropical rain forests. If, as has been stated, a 10-12% of them should possess biological activity, it could be assumed that there are approximately 35000 plant species in this region which could be important sources of new drugs. Therefore, a great effort has to be made to carry out an in-depth investigation of this regional flora and at the same time intensify research on known medicinal plants and on those whose traditional medicinal uses are well established or should be validated.

During the last thirty years, great advances have been made in the methodology of isolation of bioactive principles from plants. These, along with newer and more precise analytical methods make it relatively easy the study of medicinal plants. Newer modern methods of separation and structural elucidation have made the identification of complex organic compounds very easy. In addition, great strides have been made in the design and use of new bioassays to detect a wide array of biological activities.

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Schultes, R.E. and Raffan, R.F. The Healing Forest, Dioscorides Press, Portland, Oregon, 1990, 484 pp.

It is necessary to strengthen research groups engaged in the study of natural products using modern methods of separation and bioassays so that they can improve their efficiency in research. The rich biodiversity of this region is a valuable resource for the discovery of new drugs. It may allow us to learn more about traditional medicinal plant usages, and may serve as a source of income for Latin America.

The United Nations Industrial Organization (UNIDO) has also recognized the potential of plants in the health care and economic development. During the Second Consultation on the Pharmaceutical Industry organized by UNIDO, it recommended "the development of guidelines to assist the developing countries in the improvement of medicinal plants supply as raw materials or processed products," and "continuation of technical cooperation between the developing and developed countries in all areas concerned with better utilization of medicinal plant-based pharmaceutical industry⁷. The Third Consultation on Pharmaceutical Industry, held in Madrid also emphasized the need of industrialization of medicinal plants and their use.

In lieu of the aforementioned, it is clearly obvious that the medicinal plants represent an alternative for the health care and can be important in the

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Report of the Second Consultation on the Pharmaceutical Industry, Budapest, Hungary, 21-25 November 1983, p. 10

economic development. The Ministries of Health of this region should consider medicinal plants as drugs once their efficacy has been validated and the planification bodies should recognize the strategic importance of stimulating and supporting research in all aspects of natural resources of this region. It is necessary to establish a policy on drugs in Latin America, which stimulates research and utilization of medicinal plants.

2. PRESENT STATUS OF PLANT-BASED PHARMACEUTICAL INDUSTRY IN LATIN AMERICA.

2.1. Problems and Constraints

From the site visits and the survey conducted in Latin America, it has become evident that the plant-based pharmaceutical industry in this region is marginal or incipient and its participation in the total pharmaceutical market is very poor.

The manufacturing firms, in general, are small-scale industries that pack dried and pulverized medicinal plants, either as individual plants or mixtures or formulate them in the form of extracts. Some companies are engaged in the obtention of raw materials like solasodine, diosgenin, pyrethrins, colorants, essential oils etc. The laboratories which manufacture modern pharmaceutical dosage forms using plant extracts are very rare in Latin America. It is interesting, however, to note in the Latin American market finished phytomedicinals containing valerian, ginseng and garlic etc., which are manufactured in Europe. The industrial infrastructure is generally very poor, there is a noticeable lack of qualified personnel and frequently the quality of the final products is questionable.

According to the survey, the following causes have hindered the development of plant-based pharmaceutical industry in Latin America:

- a. Lack of awareness of socio-economic and medical benefits of this industry.
- b. Lack of manufacturing technical know how.
- c. Resilience in prescription of phytomedicinals by the physicians.
- d. Lack of a national and sectorial policy.
- e. Unawareness or lack of quality control procedures and methods of standarization.
- f. Difficulty in the availability of large quantities of medicinal plants of high quality.
- g. Lack of R & D in agrotechnology, pharmaceutical technology, therapeutic validation, etc.
- h. Problems in the registration of phytomedicinals and other legal issues.
- i. Lack of awareness of market trends.
- j. Lack of incentives to this industry by the Government, financing, tax exemptions, etc.

The national pharmaceutical industry does not appear to be predisposed to undertake the manufacture of phytopharmaceutical products, as it does not find them to be economically feasible, doesn't have the

technology and there is a lack of confidence in the acceptability of these products. Because of lack of research in national industries, it is not possible to know the commercial and medical opportunities for the phytomedicinals based on native plants. On the other hand, the governments and health authorities, in general, do not believe that industrialization of medicinal plants will have a significant impact in health care and a reference to plants is made in the context of recovering cultural values of local traditions or as a cheaper alternative because of limited resources of medical assistance to that part of the population, which in many countries, does not have access to drugs.

Both, public and private sector, in general, lack awareness of the socioeconomic and medical benefits of phytopharmaceutical products. The National Institutes of International Commerce have recently become interested in promoting exportation of medicinal plants. Only in a few countries of this region there is a serious interest in the utilization of plants. Some countries have National Commissions on the Utilization of Medicinal Plants or have National Research Programmes for their study. However, the majority of the countries do not have a well defined national policy that may stimulate industrialization of medicinal plants and their use in primary health care. Recently, there is some initiative by the Ministries of Health of this region to create Working Groups dedicated to the promotion of traditional medicine but the efforts are minimal because of the lack of institutional

support and the results until now have not been very encouraging. Moreover, the approaches, in general, are contemplative and are far from the realities of the market, which demands validated and reliable phytopharmaceutical products.

The problem of quality control and standardization of medicinal plants and phytomedicinals represents a serious constraint. Some countries have official monographs on medicinal plants and phytomedicinals but, in general, there are no well established criteria to determine purity, authenticity and quality of raw materials. The same is true of the finished products. The countries of the region, specially the ones with relatively lesser development, require more and better qualified personnel for the industrial transformation of plants into the finished pharmaceutical products. There is a dearth of chemical engineers, technicians and other related professionals. There exist in Latin America only two or three postgraduate programs in industrial pharmacy/pharmaceutical technology.

Another problem that hinders development of this sector is the difficulty in obtaining information on process technology for the manufacture of products. The availability of specialized journals and participation in the courses and international meetings on this topic is not so easy.

A general lack of acceptance of phytomedicinals by the physicians is another major obstacle. The physicians are resilient in prescribing these products. This is due to the fact that in Latin America during their training, the disciplines related to phytotherapy are not included. Countries such as Germany and France make a special emphasis on this topic. To our knowledge, there is only one country in this region in which the topic of medicinal plants, in the formation of health professionals, is included with some degree of success.

At the present time, in Latin America it is difficult to assure a continuous supply of medicinal plants of high quality and in the quantities required. This is due to the fact that the majority of the plants are collected from wild sources. With a few noted exceptions, medicinal plants are not cultivated scientifically in this region. Brazil, Cuba, and Guatemala, among others, are perhaps some of the countries that have a few organized programs. There is a lack of agrotechnological research; optimum time of plant collections is not known, neither there are on-going studies on topics such as genetic improvement, clonal micropropagation, *in vitro* cultivation of medicinal plants, postharvest treatment, domestication of wild species and generation of propagable material.

In Latin America, only a few serious ethnobotanical studies on medicinal plant use by different ethnic groups and the general public have been carried out. There are no reported studies on "economic mapping" of medicinal plants in the spontaneous flora. It is not possible to establish plant-based industries on wild flora, without assuring the quality and quantity of available raw materials that may be industrialized and without keeping in mind environmental protection and sustainable development. The information on ethnobotanical inventories is very disperse. Recently, there is an initiative by the Organization of American States, through a Natural Products Network (REDPRONAT), under guidance of the Program for Collaborative Research in Pharmaceutical Sciences of the University of Illinois to set up a medicinal flora data base called MEDFLOR (Medicinal Flora), which will document the ethnomedical uses of medicinal plants in Latin America and the Carribean.

In the Region there are only a few countries that have experience in handling multifunctional pilot- plants, one of which is financed by the UNIDO. There is an urgent need for the development of process technologies and protocols of unit processes and quality control and for the adaptation of introduced technologies.

A lack of awareness of world market trends in medicinal plants and phytomedicinals is another serious hurdle. There is a wide fluctuation in the prices of crude botanical products. The International Trade Center in Geneva, and the System of Information on International Commerce (SICE) of the Organization of American States (OAS) can provide valuable information on world markets. The countries of the region do not have electronic data-bases that can be used to access the international data bases. The majority of the Latin American governments have not made a real effort either to provide incentives for exporting medicinal plants and/or phytomedicinals. In Central America, the Commission of the European Communities has supported some projects to stimulate exports. The Latin American Economic Commission (CEPAL) has recently become interested in this topic.

2.2. Research & Development

Agrotechnological Aspects

One of the requirements for industrialization of medicinal plants is the systematic cultivation of the species after its correct taxonomic identification and the identification of its optimal chemotypes. The collection of plants

from wild sources is not acceptable because of the danger of species extinction and there is no quality control, as a result the content of the active principles is very variable. Each country must select the species that should be cultivated. Selection of the species should be based upon such factors as: climatic conditions, the abundance of the species that can be used for primary health care for the treatment of diseases for which there are no modern drugs and their export potential. Brazil for example has selected the species for cultivation based on their uses for adults: arterial hypertension, acute respiratory infections, skin affections, gynecological problems, and arthritis, and for children- diarrhoea, parasitic diseases, respiratory diseases and skin infections.

Cultivation of medicinal plants makes it possible that raw material produced be of a reliable and consistent quality in relation to its chemical composition. Cultivation of medicinal plants represents alternative crops and the countries can diversify their agricultural production.

In Latin America, some countries cultivate medicinal plants. Brazil has, in addition, a National Medicinal Plants Germplasm Center (CINERAEN) with over 43 accessions of medicinal plants.

Technology transfer for genetic improvement of plant species is a

necessity. The countries of this region need help in their research efforts to identify the areas of maximum genetic diversity in particularly important medicinal plants and other related wild species. It is necessary to carry out research on the improvement of plant collection and techniques, continuous regeneration of propagable materials for industrialization of medicinal plants, conservation and exchange of materials from their gene pools and on the biosynthesis of important phytoconstituents.

Studies are also needed to determine the optimal period of plant collection as well as on the methods of transportation and storage. Postharvest preservation is also an important area of study. Annex 5 lists plants that can be industrialized in Latin America and is based on the survey conducted in the region; these plants can be used in the health care and/or for exportation.

Formulation and Industrial Production

Another problem in the development of medicinal plants-based industry is the lack of experience in formulation and preparation of phytopharmaceutical products, as well as in the development of process technology and the quality assurance of raw materials. More experience on the preparation of simple pharmaceutical dosage forms is also needed.

Preparations based on traditional medicine should be stimulated using modern methods of industrial processing and the programs for preclinical and clinical validation of these preparations should also be stimulated and intensified. Methods for the analysis and quality control also need to be developed.

Isolation of bioactive principles guided by bioassays

One of the critical problems in the development of natural drugs has been the lack of a multidisciplinary research approach in this field. The organic chemists, even though highly qualified in Latin America, have traditionally concentrated their efforts only on isolation of organic compounds without considering their biological activity. On the other hand, only a small number of active plants have been studied chemically. The only way of improving the cost/benefit ratio in research on medicinal plants is to have an interdisciplinary approach involving botanists, anthropologists, chemists, pharmacologists, pharmacognosists, microbiologists, parasitologists, agronomists and biochemists, in order to validate appropriately the therapeutic activity of plants and when appropriate isolate pure compounds with biological activity, which may serve as leads for the development of new drugs.

In order to achieve this objective, newer technology should be implemented and knowledge on rapid and economical bioassays should be acquired to follow up biological activity in plant extracts utilized in the traditional medicine.

Research needs money. The lack of funds has been a major problem, that the developing countries face, to have the necessary infrastructure needed for research. The private sector in Latin America is expected to contribute very little to improve this situation. In the first instance, State support appears to be the only alternative. However, given the present privatization tendencies, it appears unlikely that the governments will allocate sufficient resources for this work. The only option is to demonstrate the utility of medicinal plants for health care and for the economic development; this will then assure finances from both private and public sector. Moreover, the governments must define a national policy on drugs and specifically the role of medicinal plants in the health care of its people.

Lack of experience and knowledge in the developing countries is a serious barrier in technology transfer in areas such as: agronomy, process technology and quality control. In Latin America, there is a lack of flexible academic infrastructure for human resource development for the industrial and entrepreneurial positions. There are a very few natural products

research centers with a multidisciplinary and modern orientation. The ones that have such an approach should be strengthened through technical cooperation and bilateral/multilateral assistance.

The political vision of the government is a crucial factor. The development of local pharmaceutical industry will only be possible if the governments provide incentives for investments, promulgate laws that protect locally manufactured products and a clear acceptance of safe and efficacious phytomedicinals in their basic drug formularies. The National Science and Technology organizations should assign high research priority to this area.

It is necessary to initiate a concerted research program involving botany, plant genetics, agronomy, phytochemistry, pharmacology, chemical engineering, pharmacy, clinical studies and marketing oriented towards the production of phytomedicinals.

The competencies of National Research Institutes should be improved so that they can initiate endogenous research programs. Within each country, interinstitutional linkages and, at regional level, international networks should be established so that exchange of information, publication and personnel between the centers is possible.

It is important to study world markets to know the demand of medicinal plants. In this aspect, ITC and SICE⁸ can provide a good orientation; the later provides information through electronic data bases.

Latin American countries should have the following approach for the development of plant-based pharmaceutical industry:

1. Formulation of new technified products based on traditional remedies, including modern dosage forms.
2. Industrial production of standardized phytomedicinals, according to the good manufacturing practices and quality assurance programs.
3. Development of drugs through multidisciplinary research, and
4. Modernization of cultivation that can assure a constant supply of high quality plants.

2.3. Legal Context

In Latin America one of the serious problems that has hindered development of plants-based pharmaceutical industry is the lack of appropriate regulations for registration and quality control of

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phytomedicinals. Practically, all the countries of the region use U.S./F.D.A. regulations as reference for the registration and quality control of pharmaceutical products. As a consequence of the dependence of the Latin American Drug Control Organisms on FDA regulations, the registration of phytomedicinals has not been possible. The laboratories which, in the region, work on industrialization of medicinal plants face a difficult problem as their products are not accepted as drugs and these products are classified frequently as other things such as dietary supplements. The usual approach taken by the responsible regulatory agencies has been to inform of the existence of a Committee or a working Group to prepare special regulations for the registration of phytomedicinals. In reality, this is an excuse for not facing and solving the problem. What is evident is that these agencies, while recognizing the problem, do not provide a solution and as a result there is, on one hand, lack of quality control of the phytomedicinals which are manufactured and, on the other hand, the industry feels unprotected because of disloyal competition, and thus does not invest. In addition, there is a difficulty in patenting phytomedicinals. There is some initiative regarding this situation, specially in Europe, which can serve our region to solve this problem.

Phytomedicinals are sold in Europe as drugs mainly through the pharmacies. These products are very often prescribed by the physicians and are approved by the the Ministries of Health of the corresponding countries

as safe and effective drugs. These products are widely accepted by the consumers and represent currently a market of approximately US \$ 3 billion in western Europe.

Some of the European phytomedicinals include preparations with Ginkgo biloba, chamomile, garlic, valerian, Echinacea, mint, etc. Although Echinacea is a native American drug and once had official status in the NF, even though used widely in Europe, is not approved as a drug in the United States.

The European-American Coalition (EAPC), a consortium of manufacturing concerns of phytopharmaceutical products, believes that the systems of "over the counter" (OTC) monographs in the United States could be adopted to include phytomedicinals. These OTC products in the United States are sold without prescription and there is scientific information which establishes their efficacy and innocuousness as drugs in United States.

The treatment of medicinal plants as "old drugs" under the OTC Revision may be a convenient legal procedure for the regulation of phytomedicinals in this region.

According to the present FDA regulations, the registration of a herbal

drug should first pass through the New Drug Application (NDA) procedure. The high cost of this process for unpatentable products does not allow the pharmaceutical companies to make registration requests of their products as OTCs. The process of drug revision in the United States, is mainly for single drugs or molecular entities which are developed for use under prescription. The Latin American countries, by recognizing the U.S.P. as their official compendium, have copied these regulation in their drug registration and control laws.

Phytomedicinals on the other hand, contain whole plants or their extracts or a standardized extract of a herb (where the presence of one or more natural compounds present is guaranteed at a constant level). Thus, the phytomedicinals may contain dozens or even hundreds of natural compounds in one preparation. The procedure required for an NDA approval discourages the initiation of this procedure for the phytomedicinals .

Germany is perhaps the only developed country that permits the marketing of phytomedicinals, provided they have been proven safe and effective (Keller, 1991). However, the proof required is very different from the one required by the FDA. The German position may be considered as of "reasonable certainty" that involves use of data from the existing literature, anecdotal information supplied by practicing physicians, as well as limited

clinical studies. Because the costs involved are not exorbitant, a large number of relatively small pharmaceutical manufacturers market a wide variety of phytomedicinals in Germany. They also conduct research on them both in-house and by sponsoring investigations in university laboratories.

Some of the Latin American authorities think that the countries of the region should adopt French regulations for the control and registration of phytomedicinals. In a near future, the countries of the European countries should harmonize their regulations related to this issue. Latin American countries should be alert to see what are the final decisions taken by these countries on this important matter.

Because the active principles of many phytomedicinals currently marketed are either complex mixtures or are not yet identified, many such drugs are offered as plant extracts rather than as single chemical entities. Two such important preparations are: Gingko biloba, the best-selling prescription drug in Germany today, is widely used to stimulate cerebral circulation in the elderly. This drug cannot be registered in the United States. Since the majority of the Latin American countries recognize the U.S.P. as the official compendium, this product is also not available legally in this region as a drug. Similar is the case with the Echinacea preparations, widely used in Germany as immunostimulants and for the treatment of colds and flu. This

list could be extended, but these examples demonstrate the need for a more pragmatic regulatory climate that can facilitate the development of phytomedicinals.

Other manner of stimulating the industry, could be the procedure utilized for orphan drugs in the United States. The Orphan Drug Act provides incentives such as seven year market exclusivity to developers of drugs targeted to a rare disease or condition that afflicts less than 200,000 patients in the United States⁹. Some thing similar could be extended to the manufacture of phytomedicinals. It is important that countries and international organizations like the World Health Organization bring influence to bear on the Ministries of Health to modify their regulations for phytomedicinals.

There is at present an enormous interest in herbs among common people. Only in the United States, the general public spends half a billion dollars per year on them in health food stores alone¹⁰. If we include the sale of herb teas in the supermarkets, this figure would have to be multiplied many times.

⁹ Anderson, K. and Anderson, L.E. Orphan Drugs, Body Press, Los Angeles, 1987, 253 pp.

¹⁰ Geselwitz, G. ed Health Food Business 37(3): 45, 1991.

A very few Latin American countries have their own pharmacopoeia. Brasil and Mexico are presently revising their Pharmacopoeia. It appears that monographs on medicinal plants will be included in them. This will facilitate their industrialization and use.

3. PLAN OF ACTION AND STRATEGIES FOR INDUSTRIAL UTILIZATION OF PLANTS.

In Latin America, because the majority of the population does not have access to drugs and the governments are not in a position to improve the health care coverage, medicinal plants represent one of the most viable alternatives. Phytomedicinals which may be manufactured in the region should be in the form of simple dosage forms, which are stable and economical and based principally upon the use of standardized plant extracts of proven efficacy and innocuousness. The countries of this region cannot have the luxury of utilizing sophisticated technologies of advanced drug delivery systems with known kinetics, as the costs will be prohibitive. What really matters is that the medicinal plants used are effective and non toxic. As value added cost for industrial transformation of medicinal plants increases, so will the difficulty of the people to obtain them. It would be a paradox that the use of phytomedicinals is stimulated among those who have no access to modern drugs and once manufactured, their cost is so high that it becomes out of reach of the needy.

3.1. Plant Extracts

Preparation of pure or total plant extracts, standardized qualitatively and quantitatively, appears to be a viable, ethical and an economic alternative.

Plant extracts have been used since millenium in all parts of the world in the form of simple and traditional preparations of therapeutics agents. An industry based on these preparations will require the following:

- Botanical and agronomical studies on plant species utilized. In order to establish a plant-based pharmaceutical industry, it is necessary to carry out "economic mapping" studies to know the quantity of raw material available. Without this information, there is an imminent danger of extinction of the species.
- Conservation of germplasms of medicinal plant species, and their cultivation to assure a continuous supply and to minimize biological variation. In Latin America, in vitro plant tissue-culture studies for the propagation of the species should also be stimulated. Studies should be conducted to determine the evolution curve of active principles in the plant so that it can be collected at a time when its content is maximum.
- Bioactive principles in the plant used should be identified; this can be done on the basis of published literature.
- Adequate analytical methodologies for the qualitative and quantitative assay should be established for diverse phytoconstituents, and for quality control of plant material and their extracts.
- Studies should be conducted:

- . on the best extraction method, with respect to the choice of solvent and technology to be used.
- . to develop most appropriate pharmaceutical formulations of the extract (granules, syrup, liquids, etc) which have an optimum stability, easy dosification, good presentation and high quality.
- . on pharmacological, toxicological and clinical aspects. Now a days there exist a variety of in vitro bioassays that permit easily the detection of biological activity in plant extracts. Studies should also be conducted to validate seriously the plant utilized in order to guarantee its efficacy and innocuousness.

The use of plant extracts with well defined characteristics and of modern instrumental techniques for quality assurance allows production of phytomedicinals in a variety of standardized and stable pharmaceutical dosage forms and the populations with little resources can have an access to them.

3.2. Research

The modern pharmaceutical research on medicinal plants is oriented towards:

- a. Evaluation of biological activity of plants to determine their efficacy,

innocuousness and toxicity.

- b. Isolation of pure active compounds, determination of chemical structures and synthesis of the product and its analogues.

Whenever possible this research approach should be used, keeping in mind isolation of pure active principles by bioassays-guided fractionation. Research programs should also include topics related to the acceptability and utilization of plant-based phytomedicinals.

Medicinal plants used in traditional medicine should be studied and research should concentrate on a priority list of plants that can be used for the treatment of more prevalent diseases or on the basis of the plants which can be potentially cultivated and exported (Annex 5).

Research centers should be capable of providing services to the productive sector. It is necessary to establish mechanisms for commercialization of results, to develop confidential contractual agreements and patents between the industry and the research center.

Technical assistance from research laboratories in the developed countries should be sought and collaborative research programs should be

initiated. It is also desirable to seek technical cooperation among the developing countries (TCDC) so that they can mutually help each other and generate projects with shared risks.

3.3. Human Resource Development

The lack of highly qualified personnel in different aspects related with the development of plant-based pharmaceutical industry in Latin American has been one of the major constraints. It is, therefore, strategically important to create appropriate infrastructure for human resource development both at the technical as well as the managerial levels. A comprehensive and multifacetic approach should be used to cover both the physical and technical infrastructure needed for industrial development.

Postgraduate programs leading to M.S. and Ph.D. degrees should be designed and initiated. Because of the limitation of financial resources, it is advisable that the postgraduate programs are at a regional level and in different locations, depending upon the available resources and strengths of the centers on a determined topic. Technical cooperation programs among developing countries are also advisable; through such programs, short-term and targeted training for scientists of one country in another can be easily carried out.

3.4. Regional and International Cooperation

International organizations should play a key role in stimulating the development of plant-based pharmaceutical industry in Latin America. They should offer their experiences and collective knowledge to help the countries of the region. Multilateral organizations such as UNIDO, WHO, FAO, CEPAL, OAS, IDB, and World Bank should support technical assistance projects and programs. It is most important to have coordination among these organizations to avoid repetitions. The countries should also initiate bilateral programs. The cooperation should be based on well defined objectives. Emphasis should be placed on the following cooperative actions:

- Establishment of R & D Centers and initiation of collaborative research programs on medicinal plants used for the most prevalent pathologies in Latin America or for the pathologies for which there are no adequate remedies.
- Identification and development of therapeutically active compounds of plant origin, to be included in the list of essential drugs for primary health care.
- Development of strategies that may facilitate transference of production technologies and design of quality assurance protocols for raw materials and finished products.

- Exchange of technical information and international commerce.
- Advise on the purchase of equipment/machinery
- Organization of training programs as well as exchange of experiences at technical and managerial levels.
- Identification of markets for plants and their extracts which can be manufactured advantageously from a strategic point of view of genetic diversity and climatic conditions of the region.

4. CONCLUSION AND RECOMENNDATIONS

The following recommendations were adopted by the Experts Group:

To the Government:

1. Set up a National Multidisciplinary Committee to assist the Government to formulate policies concerning all aspects of medicinal plants utilization.
2. Establish a national policy to include the use of phytopharmaceutical products in health care.
3. Approval, by the Ministries of Health, of a priority list of medicinal plants to be used for the manufacture of phytopharmaceutical products.
4. Facilitate and simplify the mechanisms for the registration of phytopharmaceutical products, taking into consideration the WHO guidelines and European models.
5. Establish quality control standards for medicinal plants and phytopharmaceutical products.

6. **Create a National Institute for the study and utilization of medicinal plants.**
7. **Support universities, research centers and institutions including agricultural institutes, for carrying out comprehensive studies on industrial utilization of medicinal plants.**
8. **Promote systematic cultivation and industrialization of medicinal plants and provide incentives for stimulating national plant-based industries.**
9. **Set up banks of germplasms, seeds and propagable materials of medicinal plants.**
10. **Offer preferential financial terms to farmers, cooperatives and business enterprises interested in establishing cultivation and industrialization of medicinal plants.**
11. **Include monographs on selected medicinal plants and their extracts in the national pharmacopoeia.**
12. **Implement measures for the conservation of medicinal flora, as set forth in the Agenda 21 of United Nations' Conference on Environment and Development.**
13. **Take measures to collect detailed statistics, under a separated entity, on the**

figures of import, export and local production of medicinal plants and their products.

14. Strengthen ECDC/TCDC cooperation.
15. Take measures to protect patent rights of the whole phytogeographic region by signing contractual agreements with industrial groups in major pharmaceutical manufacturing countries to whom the medicinal plants are supplied.

To the Universities and Research Institutions:

1. Emphasize the importance of medicinal plants and phytopharmaceutical products in the training of physicians, pharmacists and other related health professionals.
2. Stimulate the creation of specialized centers and support multidisciplinary research aimed at exploring the medicinal and economic potential of the national flora.
3. Initiate postgraduate programs in the field of medicinal plants to prepare qualified personnel in areas related to the industrial utilization of medicinal plants, with emphasis on agrotechnology, process technology, quality assessment, phytotherapy and handling of multifunctional pilot plants.

4. Prepare computerized national inventories of medicinal plant resources which allow exchange of information at a regional and interregional level.
5. Assist the Governments on establishing quality control standards and on legal aspects of registration of phytopharmaceutical products.
6. Promote exchange of scientific and technological information at regional and interregional level.
7. Establish links with the industry to provide technical assistance on different aspects of industrialization of medicinal plants.
8. Improve awareness of the public on the usage of medicinal plants and their products and disseminate the information on industrialization of medicinal plants.
9. Encourage a business outlook among the academicians to facilitate their participation in productive activities and in the industrial utilization of the local medicinal flora.
10. Conduct research on promising lead compounds obtained from medicinal plants for the development of new drugs.

To the Private Sector:

1. Establish links with universities and research centers for industrial utilization of medicinal plants.
2. Call on the National Chambers of Commerce and Industries to promote industrialization of medicinal plants.
3. Form Associations of entrepreneurs and companies interested in the industrialization of medicinal plants, in order to orient them towards the market. This organization should establish contacts with principal foreign markets, as well as have access to modern technology for the production of phytopharmaceutical and natural products.
4. Promote joint-venture agreements between firms which have technology and the knowledge of the market and those that have an access to the traditional knowledge and medicinal plant resources and/or phytopharmaceutical products.

To the International Organizations:

1. Coordinate the efforts of international organizations like UNIDO, FAO, OAS, UNESCO, IDRC, EEC, UNDP, PAHO/WHO, CEPAL, etc. which support technical cooperation programs in different aspects of medicinal plants. Join forces with already existing regional programs, such as the Iberoamerican Program

for Science and Technology for Development (CYTED), Enda-Caribe (TRAMIL), etc.

2. Organize training programs for human resource development through workshops, courses, seminars, etc.
3. Support national or regional research centers on medicinal plants and natural products which have well defined goals and relationship with the industrial sector.
4. Promote the creation of a Regional/International Medicinal Plants Research Center, similar to the International Potato Research Center in Lima or the International Rice Research Center in Philippines.
5. Facilitate access to updated information, preferably through computerized data bases on international markets of medicinal plants and the possibilities of industrial investments in this field.
6. Support the creation of networks of collaborating centers on medicinal plants similar to the WHO collaborating centers.
7. Promote cooperation between the research and development laboratories of industrialized and developing countries and among the ones in the developing

countries. This can take the following forms: exchange of germplasms and seeds, exchange of information on crops, process technology, formulation of products and marketing practices, and exchange of personnel between R & D institutions for specialized training of personnel.

8. Set up an International Committee to prepare monographs of indigenous medicinal plants, which could be used for quality control purposes.
9. Program periodical meetings, every two years on Industrialization of Medicinal Plants in Latin America and the Caribbean. The Natural Products Research Center (CIPRONA) of the University of Costa Rica offers to be the host for the next Experts' Group meeting.

ANNEX 1

PERSONS INTERVIENED AND COUNTRIES VISITED

PERU

Carlos Alberto Goulart. Representative UNIDO.

Fernando Cabieses, Manuel Fernández, Pedro Arellano y José Scheneke - Institute of
Traditional Medicine, Ministry of Health.

Salustiano Pomacondor. Department of Native Species, Ministry of Agriculture.

Ing. José Chirino. Laboratorio DIGSA.

Gerardo Garrido Pinzón. President. Sintesis Química S.A.

Luis German Zúñiga, Manager, Globe del Perú, S.A.

Rosario Valesmoro. Manager. PROINTEC

Olga Lock de Ugaz. Department of Chemistry. Pontificia Universidad Católica del
Perú.

Patricia Thorndike. Presidenta DEMETRA.

Constanza Barrera. IPIFA

CHILE

José Luis Rodríguez. Manager. NUTRISA

Gerardo Arama. Manager. Laboratorio Arama

Raquel González. Institute of Public Health, Director of Registrations.

Luis Martínez. Assistant Secretary, Ministry of Health

Ernesto González. College of Pharmacy, University of Chile.

Eduardo Medina. Director of Traditional Medicine, Ministry of Health.

Roberto Arata. Manager. Garden House Ltda.

Jorge Geraldo de Lima. Representative UNIDO.

BRASIL

Jorge Antonio Zepeda Bermudez. Executive Secretary. Ministry of Health.

Alcibiades de M. Athayde Jr. Vice President ALANAC. Laboratorio Libbs. Sao Paulo

Valdemiro D. Sgarbieri y Nikolai Sherapin, Center for Chemical, Biological and

Agronomic Research University of Campina & CODETECH CPQBA, Campinas.

Antonio José Lapa. Paulista School of Medicine, Sao Paulo.

Abelardo Vergueira. Director Sanrisil.

Franck Soudaut y Mercedes Augusto Botanical Garden of Brasilia.

Lace Medeiros Breyes. Herbarium, Federal University of Brasil

Victoria Lobo. UNIDO Representative

MEXICO

Gregorio Pruzan. UNIDO Representative

Ofelia Espejo. National Chamber of Pharmaceutical Industry.

Mariana Meckes. Pharmacology of Natural Products Research Unit, Mexican Institute
of Social Security.

Rogelio Pereda - Miranda. Department of Pharmacy, National Autonomons University
of Mexico, UNAM.

Alfonso López González, Director of Primary Health Standards and Integral Family
Medicine, Secretary of Health.

CUBA

José I. Goicochea. Vice Minister of Health for Pharmaceutical Industry.

Menno Van Hilten. UNIDO Representative

Dolores Marrero y Graciela del Cueto. State Commission for Economic Collaboration
CECE.

Miguel Márquez. PAHO/WHO Representative.

Basilía Lahens. National Director of Pharmacy

Teresa Guerrero y Francisco Moron. Science and Technology Directorate, Ministry of
Health.

Epifanio Selman. Drug Control Center.

Oscar Ross. Dean of the School Pharmacy.

Marlene Porto. Director. Center of Research on Drugs.

Augusto Simoes-López. FAO Represented

Irina Ramos. Research Center for the Development of Drugs (CIDEM)

Visit to the Botanical Garden.

ANNEX 2

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ANNEX 3**QUESTIONNAIRE ON THE INDUSTRIAL UTILIZATION OF MEDICINAL
PLANTS IN LATIN AMERICA****1. Inventory of industrializable medicinal plants and phytotherapeutic products**

- 1.1 Which plants are exported presently from your country? Are there any reliable statistics on the volume and FOB prices of these exports?
(Ministry of Commerce and Industries, Comptroller General's Office?)
- 1.2 Are there any previous national reports by national or multilateral organizations on the status of industrialization of medicinal plants in your country? Which ones?
- 1.3 Which medicinal plants or extracts and in what quantities are imported by your country as raw materials for the production of pharmaceutical products?
- 1.4 Mention 20 most important medicinal plants (in decreasing order of importance) which in your opinion can be industrialized in your country
- 1.5 Are there any pharmacies, which exclusively sell phytopharmaceutical products?
- 1.6 Are phytopharmaceutical products sold in the pharmacies?
- 1.7 Are there industrial concerns which manufacture pharmaceuticals products?

- 1.8 What is the percentage of consumption of phytopharmaceutical products in relation to the total pharmaceutical products?
- 1.9 The phytopharmaceuticals products which are used in your country, are they manufactured locally or imported? From which country(ies) are they imported?
- 1.10 How is the quality of pytopharmacuetical products which are locally manufactured? Do the campanies have equipment, building, personnel etc.

2. Cultivation and Propagation

- 2.1 Are there national or regional associations which promote cultivation and export of medicinal plants?
- 2.2 Are there any established cultivation of medicinal plants in your countries? Which plants are cultivated, and which institutions, public or private, cultivate them?

3. Industrialización

- 3.1 Is there any directory of pharmaceutical industries that utilize medicinal plants in your country.
- 3.2 Which are the most important problems that have not permitted the

development of plant-based pharmaceutical industry?

- 3.2.1 Lack of awareness of socio-economic and medical benefits of this industry.
- 3.2.2 Lack of manufacturing technical know how.
- 3.2.3 Resilience in prescription of phytomedicinals by the physicians.
- 3.2.4 Lack of a national and sectorial policy.
- 3.2.5 Unawareness or lack of quality control procedures and methods of standardization.
- 3.2.6 Difficulty in the availability of large quantities of medicinal plants of high quality.
- 3.2.7 Lack of R & D in agrotechnology, pharmaceutical technology, therapeutic validation, etc.
- 3.2.8 Problems in the registration of phytomedicinals and other legal issues.
- 3.2.9 Lack of awareness of market trends.
- 3.2.10 Lack of incentives to this industry by the Government, finances and exonerations, etc.

4. Quality Control

- 4.1 Is there any special legislation for the registration of phytomedicinals or is it the same for the pure products?

5. Research & Teaching

- 5.1 Do you know of any previous technical cooperation project that the UNIDO has undertaken in your country on the utilization of medicinal plants?
- 5.2 Which centers and research institutes presently carry out research on cultivation, genetic improvement, chemistry and pharmacology of medicinal plants?
- 5.3 Are there any private or public institutions which conduct research on this topic?
- 5.4 Are the topics of phytotherapy and medicinal plants included in the training of physicians, pharmacists, and technologist?
- 5.5 Do the practicing physicians prescribe phytomedicinals?
- 5.6 Which are the potentially priority research areas and international and cooperation possibilities in this topic?

6. Perspectives of industrialización

- 6.1 Is your government (Ministry of Health, Ministry of Industries) interested in stimulating industrialization of medicinal plants. Is there any financing available for research or to the industry?

- 6.2 Are there any public or private plans to develop this type of industry in your country?
 - 6.3 What actions and recommendation do you have which can stimulate industrialization of medicinal plants in your country?
 - 6.4 What strategies should be adopted to promote this industry?
 - 6.5 What opportunities exist for the application of existent technology in your country? Will the local companies, governments be interested in cooperative projects with the countries that have developed this industry.
 - 6.6 Is there a need to train personnel for this industry?
-
7. **What are the requirements for the establishment of medicinal-plant based industry?**
 - 7.1 Assure the supply of raw materials
 - 7.2 Finance
 - 7.3 Human resource development in manufacturing technology and quality control, etc.
 - 7.4 Better acceptance by the physicians, pharmacists and the public.
 - 7.5 Interest of business community
 - 7.6 Loal cutivation with good botanical control

ANEXO 4

LIST OF PERSONS WHO ANSWERED THE QUESTIONNAIRE

Collaboration of the following Latin American scientists who answered the questionnaire to know the state of their art of plant - based pharmaceutical industry is gratefully acknowledged.

ARGENTINA	Jorge Guzmán	National University, San Luis
BOLIVIA	Tito Estevez Martini	University of San Andrés, La Paz.
BRASIL	Nikolai Sherapin	University of Campinas,
	Antonio Lapa	Paulista School of Medicine
	Mercedes Augusto	Brasilia
COSTA RICA	Rafael Ocampo	Central Americal Tropical Agricultural

		Educational and Research Institute (CATIE)
	Gerardo Mora	Natural Products Research Center, (CIPRONA), University of Costa Rica
CHILE	Eduardo Medina C.	Traditional Medicine Unit
CUBA	Irina Ramos	Research Center for Drug Development (CIDEM)
ECUADOR	Victo Hugo Villacrés	Central University of Ecuador
EL SALVADOR	Salvador Castillo	University of El Salvador
GUATEMALA	Armando Cáceres	FARMAYA and University of San Carlos
	Lidia Girón	Farmaya
HONDURAS	Jorge Mendoza Lilian Velásquez	CHEMEX National Autonomous University of Honduras
NICARAGUA	Dylia Saavedra Uriel Sotomayor Eduardo de Trinidad	National Autonomous University of León CNMPT, Esteli CNMPT, Esteli

PANAMA	Esperanza Montenegro Mahabir P. Gupta	Farmacia Botánica Pharmacognosy Research Center, University of Panama
PARAGUAY	Esteban Ferro	National University of Asuncion
PERU	Fernado Cabieses Patricia Thorndike	National Institute of Traditional Medicine Demetra

ANNEX 5

LIST OF POTENTIALLY INDUSTRIALIZABLE MEDICINAL PLANTS IN
LATIN AMERICA

Name	Part used	Product	Cultivated	Wild
<i>Agave sisalana</i>	Juice	Hecogenin	+	
<i>Ageratum conyzoides</i>	Whole plant	Extract	+	+
<i>Achillea millefolium</i>	Whole plant	Chamazulene	+	
<i>Aloe sp.</i>	Gel from the leaf	Alain	+	+
<i>Allium sativum</i>	Bulb	Aliicin	+	
<i>Ambrosia cumanensis</i>	Whole plant	Extract		+
<i>Ammi visnaga</i>	Fruit	Visnagin; Cheline		+
<i>Ananas comosus</i>	Juice, Stem	Bromelain	+	
<i>Andira araroba</i>	Stem wood	Total extract		+
<i>Anethum sp.</i>	Fruit	Essential oil/anethol	+	
<i>Aplopappus baylahuen</i>				
<i>Artemisia annua</i>	Plant	Artemisinin	+	
<i>Bixa orellana</i>	Seeds	Bixin/norbixin/ extract	+	
<i>Byrsonima crassifolia</i>	Fruit	Proanthocyanidins	+	
<i>Calea urticifolia</i>	Leaf	Sesquiterpene lactones		+
<i>Capsicum annum</i>	Fruit	Oleoresin; capsaicin	+	+

Name	Part used	Product	Cultivated	Wild
<i>Carica papaya</i>	Latex	Papain	+	
<i>Carum carvi</i>	Fruit	Essential oil	+	
<i>Cassia fistula</i>	Leaf	Sennosides	+	
<i>Catharanthus roseus</i>	Leaf & root	Vinblastine; Vincristine	+	+
<i>Cecropia glaziovii</i>	Leaf	Extract	+	+
<i>Centella acuminata</i>	Root	Emetine	+	
<i>Cephaelis ipecacuanha</i>	Root	Emetine/cephaeline	+	+
<i>Cestrum parqui</i>	Leaf & stem	Steroidal saponins		+
<i>Chenopodium ambrosioides</i>	Flowers and aerial part	Essential oil Ascaridol	+	+
<i>Chondrodendron tomentosum</i>	Powder	Tubocurarine	+	+
<i>Tanacetum parthenium</i>	Whole plant/flower	Parthenolides, Germacranolides	+	
<i>Cinchona</i> sp.	Bark	Quinine/Quinidine	+	+
<i>Cissampelos pareira</i>	Leaf & roots	Cissampeline	+	+
<i>Claviceps purpurea</i>	Sclerotium	Alkaloids	+	+
<i>Cola nitida</i>	Seed	Total extract	+	+
<i>Costus speciosus</i>	Rhizome	Diosgenin		+
<i>Croton lechleri</i>	Sap	Thaspine/Lignans		+
<i>Curcuma longa</i>	Rhizome	Curcumin; oleoresin	+	
<i>Cymbopogon citratus</i>	Leaf	Essential oil	+	

Name	Part used	Product	Cultivated	Wild
<i>Datura</i> sp.	Leaf/root	Scopolamine; Hyosciamine	+	
<i>Digitalis lanata</i>	Leaf	Digoxin	+	+
<i>Dimorphandra gardneriane</i>	Fruit	Rutin	+	+
<i>Dioscorea deltoidea</i>	Tubercles	Diosgenin	+	+
<i>Dioscorea composita</i>	Tubercles	Diosgenin	+	
<i>Duboisia myoporoides</i>	Stem	Hyosciamine; Hyoscine	+	
<i>Echinacea purpurea</i>	Leaf	Echinacine B; Echinocosides; extract		
<i>Equisetum bogotense</i> spp.	Stem	Extract	+	+
<i>Eucalyptus globulu citriodora</i>	Leaf	Essential oil eucalyptol	+	
<i>Foeniculum vulgare</i>	Seed/Fruit	Essential oil fenchone		
<i>Glaucum flavum</i>	Leaf	Glaucine		+
<i>Gliricidia sepium</i>	Leaf, bark, seed	Extract	+	
<i>Hamelia patens</i>	Aerial parts	Alkaloids; steroids; saponins; tannins		+
<i>Hibiscus sabdariffa</i>	Flower	Flavonoids/extract	+	
<i>Ilex guayusa</i>	Leaf	Caffeine, theobromine		+

Name	Part used	Product	Cultivated	Wild
<i>Justicia pectoralis</i>	Whole Plant	Extract/blue colourant		+
<i>Krameria triandra</i>	Root	Tannins	+	
<i>Leonotis nepetaefolia</i>	Leaf/root	Extract		+
<i>Liquidambar styracifolia</i>	Balsam	Balsam		+
<i>Lippia alba</i>	Leaf	Extract; essential oil	+	+
<i>Lippia dulcis</i>	Leaf/flower	Hernandulcin/essential oil	+	+
<i>Lippia graveolense</i>	Leaf	Essential oil		+
<i>Linum usitatissimum</i>	Seed	Fixed oil	+	
<i>Maytenus ilicifolia</i>	Leaf/aerial parts	Maytanosides/extract	+	+
<i>Melissa officinalis</i>	Leaf	Essential oil	+	+
<i>Mentha arvensis</i>	Whole plant	Essential oil	+	
<i>Mentha piperita</i>	Whole plant	Menthol/essential oil	+	
<i>Mikania glomerata</i>	Leaf	Coumarin; diterpenes	+	
<i>Myroxylon balsamum</i>	Balsam	Balsam		+
<i>Myroxylon toluiferum</i>	Balsam	Balsam		+
<i>Mucuna pruriens</i>	Beans	(L)-Dopa	+	+
<i>Neurolaena lobata</i>	Leaf	Germacranolides	+	

Name	Part used	Product	Cultivated	Wild
<i>Ocimum basilicum</i>	Leaf	Essential oil	+	
<i>Ocotea glaziovii</i>	Whole Plant	Glaziovine	+	
<i>Operculina macrocarpa</i>	Resin	Jalap		+
<i>Orthosiphon stamineus</i>	Whole Plant	Extract	+	
<i>Papaver bracteatum</i>	Latex/whole plant	Thebaine	+	
<i>Passiflora sp.</i>	Whole plant	Total extract/ passiflorine	+	+
<i>Passiflora edulis</i>	Whole plant	Extract	+	+
<i>Paullinia cupana</i>	Whole Plant/seed	Soft drinks	+	+
<i>Piper methysticum</i>	Fruit/Leaf	Kawain		+
<i>Petiveria alliacea</i>	Whole Plant	Essential oil; trisulfides		+
<i>Peumus boldus</i>	Leaves	Boldine	+	
<i>Phyllanthus acuminatus</i>	Whole plant	Phyllanthosides	+	
<i>Phyllanthus niruri</i>	Whole plant	Phyllanthosides	+	
<i>Pilocarpus cearencis</i>	Leaf	Pilocarpine	+	+
<i>Pilocarpus microphyllus</i>	Leaf	Pilocarpine	+	+
<i>Polypodium aureum</i>	Rhizome	Ecdysones	+	+
<i>Psidium guajava</i>	Fruit/bark/leaf	Guayaverine/Tannins flavonoides	+	
<i>Psoralea glandulosa</i>	Leaf	Psoralens		+
<i>Quassia amara</i>	Wood	Quassinoids	+	

Name	Part used	Product	Cultivated	Wild
<i>Quercus</i> sp.	Bark	Tannins		+
<i>Rauvolfia tetraphylla</i>	Root	Reserpine		+
<i>Rhamnus purshiana</i>	Bark	Crude extract	+	
<i>Ricinus communis</i>	Seeds	Fixed oil	+	+
<i>Rosmarinus officinalis</i>	Leaf/flower	Rosmarinic acid/ essential oil	+	
<i>Ruta graveolens</i>	Whole Plant	Rutin	+	+
<i>Sambucus mexicana</i>	Leaf/flowers/bark	Extract	+	
<i>Senna angustifolia</i>	Leaf	Sennosides	+	
<i>Senna reticulata</i>	Leaf	Sennosides	+	
<i>Silybum marianum</i>	Fruit	Silimarine	+	
<i>Simarouba glauca</i>	Fruit	Quassinoides		+
<i>Smilax medica</i>				
<i>Smilax</i> sp.	Root	Sarsapogenin	+	+
<i>Solanum</i> sp.	Fruit	Solasodine	+	+
<i>Stevia rebaudiana</i>	Leaf/Flower	Steviosides	+	
<i>Tagetes lucida</i>	Whole plant/leaf	Essential oil herniarine	+	+
<i>Taraxacum officinale</i>	Root	Resin and total extract		+
<i>Theobroma cacao</i>	Bean	Theobromine	+	
<i>Thevetia neriifolia</i>	Seeds	Peruvioside	+	

Name	Part used	Product	Cultivated	Wild
<i>Thymus vulgaris</i>	Leaf	Essential oil/Thymol	+	
<i>Uncaria tomentosa</i>	Leaf	Powder	+	
<i>Valeriana officinalis</i>	Rhizome	Valepotriates	+	+
<i>Vinca minor</i>	Leaf	Vincamine	+	+
<i>Zingiber officinale</i>	Rhizome	Zingiberine; oleoresin	+	

ANNEX 6**ACKNOWLEDGEMENTS**

The author wishes to express his sincere thanks to Prof. Dr. Mahabir Gupta, Director of Pharmacognostic Research Center on Panamanian Flora (CIFLORPAN) for his help in the preparation of this report, specially the list of industrializable medicinal plants.

Thanks are also due to Professors Nikolai Sharapin of Brasil and Armando Cáceres of Guatemala, for revising the manuscript and for their suggestions.

Guatemala, July, 1993.

**ANNEX 3
THE WORKSHOP PROGRAMME**

**PROJECT XP/RLA/92/069
EXPERTS GROUP MEETING ON THE INDUSTRIAL UTILIZATION OF
MEDICINAL PLANTS**

Panajachel, Guatemala 11-16 July, 1993

MONDAY, 12 JULY

- 9:00 Registration of participants
- 9:30 Inauguration and welcoming address by:
1. Dr. Amarillis Saravia Gómez, President of CONAPLAMED.
 2. Dr. Ying Lin, UNIDO Mission leader.
 3. Dr. Alfonso Fuentes Soria, Rector of the University San Carlos of Guatemala.
 4. Mr. Bruno Guandalini, Resident Representative. United Nations Development Programme (UNOP).
 5. Dr. Tuley de Silva, UNIDO Special Technical Adviser. Thanking words.
- 10:30 **Coffee break**
- 11:00 Election of Bureau (Chairman, Vice-Chairman, Rapporteur)
Objective of the meeting, Dr. Tuley de Silva.
- 11:30 Regional Overview of the Industrial Utilization of Medicinal
Plants in Latin America. Dr. Ceferino Sánchez, University of Panamá.
- 12:15 UNIDO Technical Assistance in the field of Industrial
Utilization of Medicinal Plants, Dr. Tuley de Silva Special Technical Adviser
IOT/CHEM.
- 13:00 **Lunch**
- 14:30 Main Elements of UNIDO Project Pilot Plant Processing and of
Ethnobotanical Research in Guatemala, Dr. Armando Cáceres, CONPLAMED.
- 15:00 Nepal, Dr. Asfaq Sheak, Department of Drug Administration
- 15:30 Thailand, Dr. Sasithorn Wasuwat, Thailand Institute of Scientific Research.
- 16:00 Turkey, Prof. Kemal Husnu C. Baser, Anadolu University,
Eskisehir.
- 16:30 **Coffee break**
- 17:00 Viet-Nam, Prof. Nguyen Gia Chan, Institute of Medical Materials.

TUESDAY, 13 JULY**Country Presentations on the Herbal Pharmaceutical Industry in Latin America.**

- 9:00 Argentina, Dr. Antonio Bandoni, University of Buenos Aires.
 9:20 Bolivia, Dr. Jaime Mondaca, Project of Indigenous Medicine.
 9:40 Brasil, Prof. Nicolai Sharapin, Multidisciplinary Research Centre.
 10:00 Chile, Dr. Eduardo Medina, Ministry of Health
 10:20 Colombia, Dr. Roberto Pinzón, National University of Colombia.
- 10:40 **Coffee break**
- 11:00 Costa Rica, Dr. Gerardo Mora, CIPRONA, University of Costa Rica.
 11:20 Cuba, Dr. Irina Ramos, Medicinal Research Centre.
 11:40 Ecuador, Dr. Magdalena Ponce, Pontificia Catholic University of Ecuador.
 12:00 Grenada, Dr. Guido Marcell, Produce Chemist Laboratory.
 12:20 Guatemala, Mrs. Lidia M. Girón, CONAPLAMED.
- 13:00 **Lunch**
- 14:30 Honduras, Dr. Jorge Mendoza, National University of Honduras.
 14:50 Jamaica, Dr. Manley West, University of West Indies.
 15:10 México, Dr. María Villareal, Mexican Institute for Social Security.
 15:30 Panamá, Dr. Mahabir Gupta, University of Panamá.
- 16:10 **Coffee break**
- 16:30 Paraguay, Dr. Evelio Cardozo, Ministry of Public Health.
 16:50 República Dominicana, Dr. Manuel Vásquez, University of Santo Domingo.
 17:10 Uruguay, Dr. Eduardo Alonso Paz, Chemistry Faculty.
 17:30 Venezuela, Dr. Nelson Ferrigini, University of Venezuela.
- 20:00 **Cultural Night**
 Marimba concert of INGUAT and exhibition of indigenous outfits, Hotel del Lago.

WEDNESDAY, 14 JULY

- 9:00 Programming Exercise of Technical Co-operation among Developing Countries. Dr. Ying Lin, Dr. de Silva.
- 13:00 **Lunch**
- 14:30 Programming Exercise of Technical Co-operation among Developing Countries.
- 19:00 **Cultural Night**
Performance by Folkloric Group.
FIESTAS DE MI PUEBLO, SOLOLA.

THURSDAY, 15 JULY

- 9:00 General Discussion.
- 10:30 **Coffee break**
- 11:00 Conclusion and recommendations.
- 13:00 **Lunch**
- 14:30 Adoption of Report.

FRIDAY, 16 JULY

- 9:00 Departure to Guatemala.
- 10:00 Visit to Pilot Plant, Engineering Faculty, USAC.
- 11:00 Visit to the installations of the Agronomy Faculty, USAC.
- 13:00 **Lunch**
Medical Biological Clinic HUMAB-KU
- 15:00 Visit to Sierra Laboratory.
Visit to Farmaya Laboratory.
- 18:00 Guided visit to the Popol-Vuh Museum
- 18:30 **Closing Ceremony**
Wine and cheese reception.

ANNEX 4
THE RESULTS OF BILATERAL DISCUSSIONS.
Expert Group Meeting on Industrialization of Medicinal Plants, Guatemala, 1993

PROJECT NUMBER	COOPERATION PARTNERS		BRIEF DESCRIPTION OF THE PROPOSAL
	PARTY A	PARTY B	
1	Thailand Institute of Scientific and Technological Research Sasithorn Wasuwat	Institute of Materia Medica Nguyen Gia Chan	Information exchange, study tour and training in production technology.
2	Center for Drug Research and Development (CIDEM) - Cuba Irina Ramos	Thailand Institute of Scientific and Technological Research Sasithorn Wasuwat	Pharmacological screening with emphasis on antiinflammatory, antiinfective (antibacterial and antifungal) activities.
3	Center for Drug Research and Development (CIDEM) - Cuba Irina Ramos	China Pharmaceutical University at Nanjing Jingyu Liang	Formulation of drugs from medicinal plants and quality control. Requirements for registration of products.
4	National University of Asuncion, Paraguay Evelio Cardozo	Argentinian Society of Research in Aromatic Plants Arnaldo Bandoni	Analytical techniques of aromatic plants of Paraguay.
5	Department of Drug Administration from Nepal Asfaq Shaek	Pharmacognostic Research Center, University of Panama Mahabir P. Gupta	Cultivation and industrialization of medicinal & aromatic plants. Exper from Nepal for diagnosis of potential medicinal plants for cultivation. Visit to Nepal and exchange of information.
6	National Autonomous University of Honduras Jerge R. Mendoza	Medicinal Plants Research Center Anadolu University, Eskisehir H. Husnu C. Baser	Training of a chemical engineer and chemist from Honduras in production of phytopharmaceuticals. Short-term course for training of local personnel.
7	National University of Asuncion, Paraguay Evelio Cardozo	Multidisciplinary Research Center (UNICAMP) - Brasil Nikolai Sharapin	Training in industrial development of medicinal plants of Paraguay.

THE RESULTS OF BILATERAL DISCUSSIONS.
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PROJECT NUMBER	COOPERATION PARTNERS		BRIEF DESCRIPTION OF THE PROPOSAL
	PARTY A	PARTY B	
8	Biomedical Research Center of the Mexican Social Security Institute Maria L. Villarreal/Mariana Meckes	Thailand Institute of Scientific and Technological Research Sasithorn Wastawat	Research on antiinflammatory and cardiovascular activity.
9	Technological Development Company (CODETEC) - Brasil Benjamin Gilbert	Guatemalan Social Security Institute (IGSS) - Guatemala Juan José Roca Colindres	Screening of antimicrobial activity and clinical research of plants from Guatemala to be applied in the treatment of diarrhoea and cholera.
10	Multidisciplinary Research Center (UNICAMP) - Brasil Nikolai Sharapin	Medicinals Plants Research Center Anadolu University, Eskisehir H. Husnu C. Baser	Exchange of information on technological innovation and research in a multidisciplinary research center.
11	Herbs Production and Processing Company Ltd. Asfaq Sheak	Medicinal Plants Research Center Anadolu University, Eskisehir H. Husnu C. Baser	Participation in regular training programme.
12	Department of Materia Medica Vietnam Gia Chan	Center for Drug Research and Development (CIDEM) - Cuba Irina Ramos	Research on the development of new natural drugs.
13	UNICAMP - University of Costa Rica Gerardo Mora	Medicinal Plants Research Center Anadolu University, Eskisehir H. Husnu C. Baser	Training of Costarican personnel on industrial extraction processes, fractionation and purification of active principles and essential oil extraction, purification and analysis.
14	Pharmacognostic Research Center, University of Panama Mahabir P. Gupta	Medicinal Plants Research Center Anadolu University, Eskisehir H. Husnu C. Baser	Extraction of essential oils and its utilization in order to initiate research, development and industrialization of medicinal plants.

THE RESULTS OF BILATERAL DISCUSSIONS.
Expert Group Meeting on Industrialization of Medicinal Plants, Guatemala, 1993

PROJECT NUMBER	COOPERATION PARTNERS		BRIEF DESCRIPTION OF THE PROPOSAL
	PARTY A	PARTY B	
15	Thailand Institute of Scientific and Technological Research Sasithorn Wasuwat	Biomedical Research Center of the Mexican Social Security Institute María L. Villarreal/Mariana Meckes	Establishment of multidisciplinary team for R&D, industrial utilization of herbal medicine from medicinal and aromatic plants. Training in pharmacology and essential oil distillation.
16	China Pharmaceutical University at Nanjing Jingyu Liang	Surco Guatemala Héctor Aristondo	Cooperation between chinese and Guatemala traditional medicine groups and application of medicinal plants to reduce illness in Guatemala. Chinese doctor to train local personnel.
17	Biomedical Research Center of the Mexican Social Security Institute María L. Villarreal/Mariana Meckes	Traditional Medicine Unit Ministry of Health - Chile Eduardo Medina	Advise the Ministry of Health to incorporate the herbal medicine into primary health care.
18	Multidisciplinary Research Center (UNICAMP) - Brasil Nikolai Sharapin	Traditional Medicine Unit Ministry of Health - Chile Eduardo Medina	To create the bases to organize the cultivation of medicinal plants and industrial production in Chile
19	Guatemalan Social Security Institute (IGSS) - Guatemala Juan José Roca	Mexican Institute of Social Security (IGSS) - Mexico María Luisa Villarreal	To investigate the medicinal plants with therapeutic properties and create a blend for the treatment of bacterial diarrhea and cholera.
20	Catholic University of Ecuador María Juana Ponce	Mexican Institute of Social Security (IGSS) - Mexico María Luisa Villarreal	To determine the promising species of medicinal plants of Ecuador; create a germoplasm bank; tissue culture; ethnobotany; and phytochemistry.
21	Faculty of Pharmacy, Central University - Venezuela Nelson Ferrigni	Multidisciplinary Research Center (UNICAMP) - Brasil Nikolai Sharapin	Implementation of agrotechnological and agrobiological studies of medicinal plants.

THE RESULTS OF BILATERAL DISCUSSIONS.
Expert Group Meeting on Industrialization of Medicinal Plants, Guatemala, 1993

PROJECT NUMBER	COOPERATION PARTNERS		BRIEF DESCRIPTION OF THE PROPOSAL
	PARTY A	PARTY B	
22	Center for Drug Research and Development (CIDEM) - Cuba Irina Ramos	Multidisciplinary Research Center (UNICAMP) - Brasil Nikolai Sharapin	Implementation of agrotechnological and agrobiological studies of medicinal plants.
23	PROMENAT Laboratories - Bolivia Rolando Mondaca	FARMAYA Laboratories - Guatemala Lidia M. Girón	To open the Bolivian market for FARMAYA product and the Guatemalan market for PROMENAT products.
24	Department of Pharmacy, National University of Colombia Roberto Pinzón	Multidisciplinary Research Center (UNICAMP) - Brasil Nikolai Sharapin	To receive training in Brasil, to create the conditions to initiate industrialization programs.
25	Drug Control, General Direction of Health Services Marta Regina Fernández	Faculty of Pharmacy and Biochemistry University of Buenos Aires Arnaldo Bandoni	Legal aspects for the control, analysis and commercialization of phytotherapeutics products.
26	Center for Drug Research and Development (CIDEM) - Cuba Irina Ramos	National Autonomous University of Honduras Jorge R. Menloza	Training of pharmacists and chemical engineers in production processes and analysis of natural products, and the creation of the course of Phytochemicals in the University.
27	Faculties of Pharmacy and Agronomy University of San Carlos Beatriz Medinilla/Myrna Herrera	Multidisciplinary Research Center (UNICAMP) - Brasil Nikolai Sharapin	Training and research development on specific problems of medicinal plants.
28	FARMAYA Laboratories - Guatemala Lidia M. Girón	National Autonomous University of Honduras Jorge R. Menloza	Training Honduran personnel in FARMAYA in the formulation and quality control for phytopharmaceuticals.
29	Mexican Institute of Social Security (IGSS) - Mexico María Luisa Villarreal	Multidisciplinary Research Center (UNICAMP) - Brasil Nikolai Sharapin	Training and technical assistance from Brasil with UNIDO financial support.

THE RESULTS OF BILATERAL DISCUSSIONS.
Expert Group Meeting on Industrialization of Medicinal Plants, Guatemala, 1993

PROJECT NUMBER	COOPERATION PARTNERS		BRIEF DESCRIPTION OF THE PROPOSAL
	PARTY A	PARTY B	
30	CEMAT-FARMAYA Guatemala Lidia M. Girón	Multidisciplinary Research Center (UNICAMP) - Brasil Nikolai Sharapin	Standardization of extracts, preparation of standards and definition of norms and standards.
31	VITA-PLANT Laboratories Venezuela	Multidisciplinary Research Center (UNICAMP) - Brasil Nikolai Sharapin	Production processes development for industrialization of phytopharmaceuticals.
32	Autonomous University of Santo Domingo - Dominican Republic Manual Vásquez Tineo	Multidisciplinary Research Center (UNICAMP) - Brasil Nikolai Sharapin	Training medicinal plants processing from collection to production of final product.
33	Drug Control, General Direction of Health Services Marta Regina Fernández	Multidisciplinary Research Center (UNICAMP) - Brasil Nikolai Sharapin	Legal aspects for the control, analysis and commercialization of phytotherapeutic products.
34	School of Pharmaceutical Sciences University of San Carlos Amarillis Saravia	Multidisciplinary Research Center (UNICAMP) - Brasil Nikolai Sharapin	Participation in the course on phytopharmaceutical technology, quality control and extraction of active principles.

**Backstopping Officer's Technical Comments
based on the work of C. Sanchez Jorquera,
XP/RLA/92/069/11-51**

The report prepared by the Consultant was presented at the Expert Group Meeting on Industrial Utilization of Medicinal Plants held in Panajachel in Guatemala from 11-17 July 1993.

The paper contains a detailed assessment of the current status of development of the sub-sector and was very useful in identifying the issues to be discussed. His recommendations were accepted with slight modifications. The report will provide the background information needed to develop projects for technical assistance. The consultant has fulfilled his obligations as detailed in his job description.