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**INTEGRATED DEVELOPMENT OF INDUSTRIAL UTILIZATION
OF MEDICINAL AND AROMATIC PLANTS
IN COUNTRIES OF ASIA AND THE PACIFIC REGION**

Issue paper *

Prepared by
the UNIDO Secretariat

*This document has not been edited.

Table of contents

	<u>Page</u>
Introduction	1
PART I: BACKGROUND	2
1. Role of medicinal plants - and an overview of the plant-based industry: Prospects and constraints	2
2. Proposal for a regional consultation meeting on industrial utilization of medicinal and aromatic plants in Asia and the Pacific during 1993	4
PART II: PROPOSED TOPIC FOR DISCUSSION AT THE REGIONAL CONSULTATION	5
<i>The Issue: The integrated development of the industrial utilization of medicinal and aromatic plants in Asia and the Pacific region</i>	6
3. General discussion of the issue: Policies, strategies, methodologies and major elements for development of the subsector	6
A. Policies covering health, agricultural, industrial and trade aspects, etc.	8
<i>A few suggested approaches - page 10</i>	
B. Agrotechnology and process technology for industrial-scale production of herbal preparations, phytopharmaceuticals, aroma chemicals and essential oils; Quality assurance, pharmacological evaluation and regulatory requirements	10
<i>A few suggested approaches - page 15</i>	
C. Need for strengthening research and development activities	15
<i>A few suggested approaches - page 17</i>	
D. Human resource development for specialized technical and management skills; Entrepreneurship and marketing aspects	18
<i>A few suggested approaches - page 19</i>	
E. Regional and international co-operation for the development of the subsector	19
<i>A few suggested approaches - page 21</i>	
PART III: CONCLUSIONS AND CONSIDERATIONS ON SOME MEASURES FOR THE DEVELOPMENT OF THE SUBSECTOR	22

Introduction

The System of Consultations and the pharmaceutical sector - the medicinal and aromatic plant-based subsector

1. The statistics on pharmaceuticals suggest that 75 per cent of the world population living in developing countries lacked access to modern medicine and consumed about 21-22 per cent of the world's pharmaceutical production. The 1990 studies also reveal that estimated production of pharmaceuticals in developing countries was around 21 per cent of global figures.

2. In its promotion of industrial development, UNIDO has endeavoured to allocate first priority to industrial activities that meet the fundamental needs of the people in developing countries. Pharmaceutical products are essential to ensuring both the immediate and long-term welfare of society, they have a major impact on people's health, their social well-being and economic performance. Consequently, many developing countries consider the pharmaceutical industry a strategic area for development.

3. UNIDO recognizes the validity of this approach and has focused upon the development of the pharmaceutical industry. It has devoted considerable efforts and resources to strengthening this industry in fields of both preventive and curative medicine, including the one based on medicinal plants.

4. UNIDO has so far convened three Consultation meetings in the pharmaceutical sector. The last was the Third Consultation on the Pharmaceutical Industry, held in Madrid, Spain, from 5 to 9 October 1987. This Consultation laid special emphasis on the industrial utilization of medicinal and aromatic plants and there was a general recognition of the importance of herbal medicine and drugs derived from medicinal plants that play a vital role in health-care programmes of large segments of the world's population.

5. It is recognized that, besides technological benefits, there are benefits of social welfare, economic and logistic nature of vital importance if one considered natural products from plants, particularly phytopharmaceuticals, their intermediates, aroma chemicals and essential oils, as a single group within a development programme. Thus, there is need for integrated development of the subsector. For effective materialization of the same, a series of prerequisites and actions at national, regional and international levels, including by organizations like WHO, UNIDO, FAO, ITC, etc., call for attention.

6. The region of Asia and the Pacific was chosen for the first Regional Consultation on the Industrial Utilization of Medicinal and Aromatic Plants because of its particular advantages compared to other regions, such as availability of well-documented knowledge, as is evident for instance from Chinese, Indian, Japanese, Korean and Thai experiences in the field of traditional and medicinal plant-based medicine as well as abundant availability of flora in the region. Although a certain degree of economic and technical co-operation exists at present in this field among the countries of the region, there is good scope for further expanding this co-operation to facilitate systematic development of this subsector.

PART I: BACKGROUND

1. Role of medicinal and aromatic plants - and an overview of the plant-based industry: Prospects and constraints

7. The importance of medicinal plants as source of therapeutic agents and contributor towards health care programmes and economies of both developing and industrialized countries is well established. The earliest medicines used were obtained from plants as plants were available in the immediate environment. Ethno-medical traditions resulted through trial and error methodology in selection of plants for treatment over long periods. In many cultures such as Chinese, Indian, Japanese, Korean, Arab, etc., the experience got systematically recorded and incorporated into a regular system of medicine and became a part of materia medica of the traditional system of medicine.

8. The World Health Organization (WHO) estimates that perhaps 80 per cent of the world population rely chiefly on plant-based traditional medicines for their primary health care needs in view of their cultural acceptance, as well as lack of easy access to modern medicines. In many cases, they bridge the gap between the availability of and demand for medicines.^{1/} Until late in the 19th century such was the situation in developed countries as well. In industrialized countries to provide herbal products, industrial units had taken up manufacturing and pharmacists started to rely upon commercial sources of standardized phytopharmaceuticals while in developing countries this was done by small-scale industries or physicians themselves and many of these were processed in kitchens. With the passage of time, the industrial revolution reflected its impact on this industry, too.

9. The work of the early part of the 20th century brought an evolution of the pharmaceutical industry, the active ingredients isolated are essential drugs today. The know-how acquired from the development and operation of medicinal plant processing factories contributed to the general evolution of research methodology in the pharmaceutical industry. As stated earlier, until the 19th century even conventional medicine depended largely on crude drugs. During the 20th century, the progress in chemical techniques and with the growth of the pharmaceutical industry, crude drugs have been replaced gradually by pure chemical drugs. A decline in popularity of medicinal plant therapy was noticed at one time but the pendulum has again swung and resurgence of interest in study and use of medicinal plants has come about. Many traditional remedies are in therapeutic use, including plants as such, or extracts prepared in accordance with the pharmacopoeia of the country where they are used; in any case, all such products when they have pharmaceutical claims must be controlled for their constancy, safety and efficacy.

10. Medicinal plants have been found to be valuable in modern medicine in four basic ways: (i) they are used as source of direct therapeutic agents, (ii) they serve as a raw material base for the elaboration of more complex semi-synthetic chemical compounds,

^{1/} Medicinal Plants in Therapy - Bulletin of the World Health Organization, 63(6).

(iii) the chemical structures derived from plant substances can be used as models for new synthetic compounds, (iv) and plants can be used as taxonomic markers for the discovery of new compounds.

11. It is beyond doubt that the prospects of an industry ultimately depend on the confidence of its consumers. The introduction of a comprehensive mix of policies and measures covering elements such as regulatory system, agricultural and industrial production, quality control, research, cost and trade, etc. at national and international levels and harmonization of such steps are likely to be of great significance for the developmental process of the plant-based medicaments subsector.

12. In developing countries, industrial-scale utilization of medicinal plants can be expected to be an effective measure for alleviating shortage of medicine for health care, and give an impetus to the development of the pharmaceutical industry. The level of development of the medicinal and aromatic plant-based subsector varies from country to country due to constraints of policy, economic and technical nature.

13. The studies reveal that the principal constraints to the development of the subsector are ideological as well as technical and economic in nature. Ideological constraints relate to the lack of official endorsement of use and acceptability of proven plant-based medicaments for health care. The other constraints relate to the lack of an adequate physical infrastructure capable of development of agricultural and industrial aspects, lack of capabilities to take advantage of modern agrotechnological techniques and practices, lack of establishment of industrial units for production on scientific and commercial scales as well as technological support in the form of research and development, quality control, pharmacological evaluation, and lack of regulatory controls, etc. In addition to the above, prevalence in developing countries of inadequacies in technical universities, training centres and human resource development institutions. And finally there is lack of entrepreneurship and non-availability of financial resources. All these aspects warrant attention and consideration, for remedial measures.

14. Aromatic plants are a good source of fragrance materials, aroma chemicals, essential oils, etc. Essential oil concentrates, such as concretes, absolutes, spice oleoresins etc. are manufactured by extraction. These are products of commercial value. Standardization and quality control of products is of great importance. For better financial returns, their production needs systematized development of agro- and processing technology and preparing of a co-ordination plan between growers, industrialists and potential buyers.

15. The development of agro-based medicaments and aroma chemical, fragrance, essential oil-based industries would have an impact on the national and rural economy. The establishment of such small-scale industries in the subsector would serve as a source of employment, particularly for women.

16. Appreciating the importance of the subject, UNIDO considers that for economic and health reasons a more systematized approach is urgently needed, that could lead to benefits for all developing countries endowed with medicinal and aromatic flora. There is need

to upgrade cultivation techniques and improve production technologies of pharmaceuticals derived from plants. There is a need for the development and enforcement of regulatory aspects. The subject as a whole lends itself to co-operation between developed and developing countries as well as among developing countries through which local resources and long-established traditions in developing countries could be wedlocked usefully to modern industrial production and health-administering technologies in developed countries. Moreover, the varied methodologies and approaches applied in the utilization of medicinal plants could interact with a view to their improvement.

17. The UNIDO approach has been for providing assistance to strengthen institutions and infrastructure for processing of medicinal and aromatic plants and quality assurance aspects. Emphasis has also been laid on assessment of indigenous flora followed by plans and programme for systematic methods for plant propagation, cultivation and crop management to ensure adequate supplies for industrial processing. UNIDO would encourage developing countries that they should seek to produce not only raw materials but as far as possible partly to fully processed plant-derived products to the specifications and standards demanded by international bodies and industrialized countries. UNIDO encourages South-South and North-South co-operation in all developmental activities.

18. In short, in providing assistance to build up developing countries' capacities in the medicinal plants field, UNIDO, in conjunction with WHO, has focused attention primarily on the following aspects:

- Selection of plant species of reputed therapeutic value and suitable for industrial processing;
- Assurance of quality and consistency in the plant raw materials;
- Validation of claims of traditional therapies using modern methodologies;
- Development of standards of quality assessment and analytical methods and pharmacological evaluation;
- Development of modern process technology bench and pilot scale as well as technology package for industrial processing;
- Development of human resources and entrepreneurship;
- Determining the role of traditional remedies in current health care programmes;
- Assistance towards development of regulatory mechanisms;
- Investigations leading to development of new drugs, particularly where current remedies are unsatisfactory or unavailable.

2. Proposal for a regional consultation meeting on industrial utilization of medicinal and aromatic plants in Asia and the Pacific during 1993

19. In the light of the ever increasing importance of the subject, UNIDO has planned to convene, in co-operation with the World Health Organization (WHO), a Regional Consultation on Industrial Utilization of Medicinal and Aromatic Plants in Asia and the Pacific during the biennium 1992-1993. The interest of the countries of the region in this field is manifested in the follow-up action undertaken since the Third Consultation on the Pharmaceutical

Industry and in the increase in technical assistance. UNIDO maintains a large portfolio of projects and interest in the subject is evident in this region, particularly in China, India, Indonesia, Iran, Nepal, Pakistan, Sri Lanka, Thailand and Vietnam.

20. The objectives of the proposed Regional Consultation are: (a) The development and strengthening of capabilities and capacities in areas of agrotechnology, technology for processing, quality control and pharmacological evaluation, research and development, regulatory mechanisms, development of human resources, entrepreneurship and marketing, so as to assure the sustained growth of the industry; (b) Promotion of regional co-operation among developing countries and between developing and developed countries in mutually beneficial areas of the phytopharmaceutical industry with the aim of improving economic exploitation of local resources. Since national approaches for the development of this subsector would be immeasurably enhanced through regional as well as international co-operation, hence the need for emphasis at these levels. Some of the proposed activities could, in fact, become viable only if such a co-operative approach is adopted.

PART II: PROPOSED TOPIC FOR DISCUSSION AT THE REGIONAL CONSULTATION

21. The development plans that could generate industrially useful products can be expected to occupy a prominent position in the list of national priorities, thus needing development of critical national capabilities, including policy framework, infrastructural, institutional, technological aspects, human skills, trade, as well as identification of financial resources, etc. Plant resources offer development of small-scale agro-based industries, such as phytopharmaceutical, aroma chemical, fragrance and essential oil, gum and resin, tannin industries with high impact on national and rural economy.

22. The primary patterns of pharmaceutical development from plants include: (a) Pharmaceuticals from plants used in traditional pharmacopoeias; (b) Plants used as raw materials for obtaining drugs already accepted in developed and developing countries' pharmacopoeias; (c) Plants as raw materials for obtaining drug intermediates and new drugs. The pattern of usage of aromatic plants is that these serve as raw materials for (a) essential oils, and (b) aroma chemicals and fragrance substances. There is need for a systematic approach to exploit the potential of these resources.

23. UNIDO has convened two workshops and a global preparatory meeting on the industrial utilization of medicinal and aromatic plants during 1990-1992. The main objectives of the activities undertaken include the following:

- To identify, within the scope of the broad theme referred to above, the specific and priority issues to be submitted to the Regional Consultation;
- To identify areas needing special attention and assess constraints to developing the subsector through policy measures and enhancement of the technological base;

- To identify ways and means to promote active subregional, regional and international co-operation and propose actions, identify technical co-operation and investment projects necessary to overcome constraints to and opportunities for developing the subsector in the region;
- To assess the prerequisites for the integration of medicinal and aromatic plant-based industry products within the national health delivery system as well as the national and rural economies.

24. The Issue: The integrated development of the industrial utilization of medicinal and aromatic plants in Asia and the Pacific region

The Global Preparatory Meeting^{2/} held in Vienna, Austria, from 18 to 20 November 1992 recommended the following five elements of the issue on integrated development of industrial utilization of medicinal and aromatic plants for submission to the Regional Consultation on the Industrial Utilization of Medicinal and Aromatic Plants in Asia and the Pacific:

- A. Policies covering health, agricultural, industrial and trade aspects, etc.;**
- B. Agrotechnology and process technology for industrial-scale production of herbal preparations, phytopharmaceuticals, aroma chemicals and essential oils; Quality assurance, pharmacological evaluation and regulatory requirements;**
- C. Need for strengthening research and development activities;**
- D. Human resource development for specialized technical and managerial skills; entrepreneurship and marketing aspects;**
- E. Regional and international co-operation for development of the subsector.**

3. General discussion of the issue: Policies, strategies, methodologies and major elements for development of the subsector

25. In general terms, to make the best use for mankind of the ethnomedical experience accumulated over millennia, certain strategic elements in drug development have to be accentuated and

^{2/} Report of the Global Preparatory Meeting for the Regional Consultation on the Industrial Utilization of Medicinal and Aromatic Plants in Asia and the Pacific, Vienna, Austria, 18-20 November 1992; UNIDO, ID/WG.531/3(SPEC.)

these must also address the contingency situation prevalent in the developing countries, as regards the restricted availability of pharmaceuticals.

26. The three key elements will be:

- To generate factory-produced plant-derived pharmaceuticals based on traditional formulations with attendant standardization and quality control and modern manufacturing practices;
- To formulate new products (preparations) based on traditional pharmacopoeias, in new dosage forms at economic prices to suit developing countries' requirements and priority being given to areas where therapies available to modern medicine are inadequate;
- To generate new natural products and related synthetic ones as new therapies in modern medicine.

27. The strategy will no doubt be of great use to the developing countries but it will also seek to benefit the industrialized world particularly where modern medicine is short of adequate therapies. The strategy should draw support from all on grounds of humanitarianism, concern for the health of the underprivileged and the need to develop industries in the poorer parts of the world. The undoubted global benefits that can accrue by the sharing of research and development in this field would be profitable to both industrialized as well as developing nations.

28. A partnership could be initiated between industrialized and developing countries as well as between developing countries themselves in order to realize the best in traditional medicines for the global benefit and to meet the present dire situation that confronts those that inhabit the less privileged parts of the world. The services of international organizations, such as UNIDO, WHO, FAO, ITC etc., could be used to catalyze the development of such partnerships, based on the work carried out by these organizations, and the experience so gained.

29. Effective exploitation of medicinal and aromatic plant resources require co-ordination between a number of sectors and consideration of some basic policy issues. It would be befitting for each country to evolve a planned approach for the development of this subsector and besides efforts at a national level, international organizations, such as WHO, UNIDO, FAO, ITC, etc., may be of assistance in implementing the plans.

30. While referring to policies and strategies, the medicinal plant-based industry and governments need to work in harmony and good working relationship. An industrial policy which supports domestic production and stimulates export needs to be developed. Governments will have to ensure that policy is formulated in a manner that makes investment in manufacturing more attractive through incentives, concessions and assistance. The manufacturers of plant-based products, like the manufacturers of other pharmaceutical products, need to be supervised by health ministries and should be guided by a national health policy. A regulatory system needs to be put into force. Considerations need to be given to development of standard formularies. Good manufacturing practices (GMP), quality assurance, harmonization of policies relating to testing and pharmacological evaluation of medicaments, safety and efficiency are some of the major aspects to be checked. In addition, pricing regulation schemes and a policy with regard to research and development need to

be developed. Above all, the ethics of the industry should at no cost be ignored. Policies with respect to the establishment of both a physical and a human infrastructure as well as investment should be developed.

31. Strategic decisions required by organizations concern the products to be produced and the market to be served and should be based on studies. Other decisions would concern the process, technologies, environmental protection, type of research and development. Particular attention and more support is needed for remedies for tropical diseases which are most common in developing countries, such as childhood diseases, diarrhoea and tuberculosis, and production of marketable products, as well as type of distribution system for products. Marketing strategies are of significant importance. It is established that marketing activities benefit greatly from economies of scale. This calls for integration, merger, acquisition, intercompany coalitions, etc. as is common practice in the pharmaceutical industry. Patent system and export orientation also need attention. The prospects for the plant-based medicaments subsector of the pharmaceutical industry undoubtedly depends on the confidence of its consumers. The policy makers and strategists ought to take into account the minutest details in order to make the industry a success and to enable it to meet the growing needs.

Systematic approach to exploit the potential of plant resources

32. The need for systematic approach to exploit the potential of the plant resources is being realized in many countries. The presence of agrotechnological and botanical expertise as well as the availability of some expertise in phytochemistry, pharmacology, and pharmaceuticals is deemed as a necessary prerequisite. Aspects covering botany, ethnopharmacology, ethnomedicine, chemistry, pharmacological activity, toxicity, agrotechnology, post-harvest technology, process technology, packaging of dosage forms of prescription and OTC products, and marketing etc. need to be surveyed and studied for better appreciation of the issues. In order to achieve success, steps would need to be taken in developing and reinforcing agro- and technological bases, information systems, research, human resources and co-operation amongst and between countries in all areas of activities. Besides the factors already enumerated, the need for the assessment of plant-based products is emphasized.

A. Policies covering health, agricultural, industrial and trade aspects, etc.

33. Providing adequate health care presents a significant and complex challenge. The objective of a national drug policy is to render accessible to the whole population the most effective and safe pharmaceutical products of established quality at reasonable cost. The aim of developing national drug policies is to improve the efficiency of the medicaments supply system through co-operation among those responsible for health, industrial production and trade, etc. The industrial aspects of drug policy are concerned with establishment of local production facilities and policy measures for its promotion, covering development of infrastructure, enhancing access to technology, domestic production, quality control, pricing, research and development, human resources, regulatory mechanisms and attractive measures for investment by providing incentives, concessions, assistance and financing on favourable terms, etc.

34. Determining the place of plant-based medicaments in the national health care programme and evolving a methodology for an integrated use of such medicine with modern medicine is worthy of continued investigation and, after due consideration, worth its while for implementation.

35. A socially desired and officially endorsed demand for phyto-pharmaceuticals and usage of traditional/herbal medicine could be of great assistance in integrating the use of these drugs with the modern medicine in order to meet national health needs. To implement this strategy, the National Health Policy would need to include a policy on phytopharmaceuticals covering continuous supply of source medicinal plants, domestic production, quality control, distribution, R&D for new drugs, and other related aspects such as legislation, registration and human resource development. The World Health Organization (WHO) can be a guiding body in this field of activity.

36. The manufacturers of plant-based medicaments, like the manufacturers of other pharmaceutical products, need to be guided by a national health policy. The cause could be better served through the establishment of a national policy and planning committee to deal with all aspects related to the development of the pharmaceutical sector, including medicaments based on medicinal plants.

Need for establishing a national policy and planning committee:

37. The first step in achieving the goal should be that the national governments should set up a national policy and planning committee drawn from government and private bodies to evolve and formulate national policies, strategies and plans for dealing with all aspects of the pharmaceutical sector, including utilization of medicinal plants. The committee should co-ordinate the functioning of different institutions and agencies and monitor progress towards the implementation of the policies in question. The committee should formulate a short- and long-term plan for this sector after due assessment of needs, priorities and resources. It could set up subcommittees dealing with specific aspects of the sector, for instance, a sub-committee dealing with the phytopharmaceutical industry and another dealing with traditional medicine as well as development of new drugs. These two sub-committees should draw up policy guidelines on issues such as:

- Introduction of subjects related to the medicinal plant-based medicaments into the curricula of the schools of health professionals and related disciplines;
- Promoting the use of traditional medicine along with modern medicine in the national health care programme, as well as public education through series of manuals, handbooks, videotapes, etc.;
- Drawing up a system of registration of traditional medicine, development of traditional drug pharmacopoeia and formulary, as well as the delivery aspect of such medicine into the primary health care programme;
- Cultivation, collection of plants, establishment of germ plasm banks, etc
- Centralizing/modernizing production facilities on an industrial scale for traditional medicine;

- Establishing a phytopharmaceutical industry in line with an enunciated comprehensive industrial policy which supports domestic production and stimulates exports.

38. In the subsector under reference, the adoption of a comprehensive approach in bringing together the main disciplines and interests concerned, i.e. health, agriculture, industry, trade, academia, under a high level co-ordinating subcommittee can be of significant assistance. Such a body would assess needs and priorities, formulate a national policy, help to mobilize resources and ensure orderly development of work and research in the field and interrelated matters stipulated by health and industry departments for the development of drug industry.

39. Practical approaches for the development of policies covering health, agricultural, industrial and trade aspects, etc. could involve, among others:

- (a) Setting-up of national policy and planning committees to evaluate the needs and resources, to formulate policies and strategies, and to develop plans for domestic development of the subsector covering all aspects, through co-operation between those responsible for health, industry and trade;
- (b) Development of pharmacopoeias, promotion of use of herbal medicine in the national health delivery system and organization of health, education and training schemes;
- (c) Establishing regulatory bodies and registration authorities for plant-based medicaments;
- (d) Measures to enhance development of industrial infrastructure, technological bases, quality assurance, and initiation of steps towards facilitation of transfer of technology, production on industrial scale, research, development of human resources and investment promotion;
- (e) Establishment of information centres for exchange of information on scientific, technological and other aspects;
- (f) Development of a policy framework for encouraging international trade, etc.

B. Agrotechnology and process technology for industrial-scale production of herbal preparations, phytopharmaceuticals, aroma chemicals and essential oils; Quality assurance, pharmacological evaluation and regulatory requirements

40. In developing countries, one of the main obstacles for the development of the subsector is lack of adequate physical and institutional infrastructure which directly affects the output,

efficiency of production units, the degree of local and regional co-operation in research and development, marketing and other supportive activities. Thus besides fulfillment of basic requirements, the efforts need to be directed towards the development of other potential areas listed hereunder, to fulfil continuous availability of materials and services.

(a) Agrotechnology:

41. The application of modern standardized techniques for the cultivation and propagation of medicinal plants needs consideration in order to meet continuous availability of quality material. The potential areas needing attention cover: Preservation, propagation, cropwise cultivation, including improved seeds, standardized cultivation techniques, steps to domesticate wild and endangered species, elimination of pests and diseases, control on heavy metals and pesticides, genetic improvement, exchange of germ plasm, post-harvest treatment and storage, etc.

42. Micropropagation techniques based on tissue culture and modern methods of genetic improvement of plant species also need consideration, besides the macropropagation method. Development and introduction of good agricultural practices need consideration.

(b) Process and development technologies:

43. The development of technologies for processing of plant materials for production of extracts, active principles, therapeutic agents as well as essential oils etc., and capabilities for production of traditional medicine and aroma chemicals on an industrial scale needs to be considered.

44. Although many developing countries export plant raw materials and import finished drugs at very high prices, production of drugs in their own countries has not commenced. The constraints to this are the non-availability of (i) technology, which in many instances is protected, and (ii) capital investment. Even if these countries could produce some of the drugs, the economy of scale of production would not be feasible unless prior marketing arrangements were established. Regional co-operation in this regard may be a favourable factor.

45. As mentioned earlier, the UNIDO System of Consultations promotes liaison between governments, industry from North and South, in particular areas of industry. Technology aspects are considered at the sectoral level. The UNIDO programme in technology transfer includes all aspects related to the selection, acquisition, adaptation, operation and maintenance of appropriate technology. The approach for any project will depend upon the specific circumstances. However, aspects which are considered in any technology transfer activity may include:

- Enhancement of awareness of technological developments;
- Training in all relevant aspects including direct technological know-how mechanisms for the acquisition of technology;
- Selection of the most appropriate technology taking into account technological, economic, energy, environmental and social aspects;
- Development of capabilities to design and install industrial units and allow local production of hardware where possible;

- Development of institutional capability to support appropriate technology transfer and cleaner production technologies.

46. Lack of finance can inhibit transfer of technology to developing countries. Beside other global and regional finance-dealing agencies, the Industrial Investment Programme of UNIDO helps in dealing with financial constraints, through its promotion of commercially oriented joint ventures between national investors in developing countries and foreign partners. The main activities of UNIDO's programme include the organization of national and regional investment promotion fora and investment promotion services.

47. The need to develop processing technology to enable developing countries not only to export plant raw materials but extracts, pure compounds or intermediates as well, is always there. Transfer of technology in the subsector implies enhancement of the level of national expertise in several disciplines that constitute the multidisciplinary exercise of the plant-derived pharmaceutical industry. This includes agronomy, chemistry, instrumental analysis, pharmacology, process technology and product formulation. In most developing countries some nucleus exists in the form of a multidisciplinary institution or centre in which the building-up of a process could begin.

48. It may be explained here that pilot plant technology is needed for development of process technology and for determining a variety of technoeconomic parameters needed for a relevant feasibility study prior to commercial batch scale processing. Along with the development of facilities for production of extracts and active principles, basic drugs, phytopharmaceutical formulations etc. the necessity of standardization of production as well as enforcing good manufacturing practices for all these operations would have significant importance. Good manufacturing practices (GMP) are the guidelines for application of the principles of quality assurance related to the manufacture, processing and packaging operations for medicaments to ensure their safety, efficacy and stability. WHO has developed GMP recommendations for pharmaceuticals as guidance for the industry.

49. In the context of process technology, to facilitate matters the local fabrication and use of versatile polyfunctional pilot scale process unit would be a step forward. To assist interested parties, UNIDO has developed a versatile polyvalent pilot scale distillation and extraction unit to process medicinal and aromatic plants. A practical modular engineering design complete with itemized scale construction drawings with representations of exploded sections and bills of quantities of the materials of construction involved for fabrication of such a unit is available.^{2/}

50. Traditional medicines have not developed with advances of technology. The age-old methods are still used in their production. This is due to two main reasons, viz. the lack of research and development activities and the unwillingness of traditional practitioners to change due to their dogmatic approach. Besides, there have not been many initiatives by governments or modern practitioners to officially use the services of the traditional practitioners and upgrade their skills.

^{2/} Design Options for a Polyvalent Pilot Plant for the Distillation of Medicinal and Aromatic Plants, IPCT.143(SPEC.)

51. With the practices of the healer himself dispensing the medicine becoming less and less, patients had to seek the help of the herbal drug store or collectors for the plant materials prescribed. This had led to inconsistencies in plant materials and extraction methods used, bringing about quality and dosage problems. Hence there is an urgent need to standardize these medicines so that those who rely on them could get a better quality drug. These could even be formulated into modern dosage forms to ensure consistent dosage stability and easy transport and storage. UNIDO has pioneered activities in this area.

52. Traditional processing methods could be stimulated, even improved and rendered simpler by use of scientific techniques and standardization in production could be achieved. Manufacturing procedures should be established and described. The use of modern process technology for production of standardized traditional therapies on an industrial scale merits serious consideration for meeting the needs of primary health care.

53. Production of traditional medicines in factories will ensure greater availability of the products with reproducible quality. Consideration thus needs to be given to simplifying and modernizing methods of production, development of appropriate quality control standards, setting-up centralized factories for production, developing new formulations and dosage forms, and determining pharmacokinetic bioavailability and bioequivalence parameters wherever feasible.

54. The commercial production calls for development of engineering capabilities. Thus designing, fabrication and installation of equipment is another area which should be attended.

55. There is a need for conducting market surveys covering all aspects with a view to adoption of proper marketing strategies pertaining to especially availability, quality, price etc.

56. Aromatic plants have been the source of flavours and aromas of food and pharmaceutical preparations. Many developing countries export the raw plant material or the crude oil or oleoresin extracted from the plants for use in perfumery, cosmetic and food industries. In spite of the advances in synthetic chemistry leading to synthetic aroma chemicals and fragrance substances, natural blends of fragrances substances still remain competitive. Some naturals are even more valued as their sensory properties cannot be imitated or matched. There is also a growing need for these in aroma therapy for those who prefer "natural" to artificial/synthetic materials.

57. Two factors have retarded the development of the essential oil industry in developing countries: (i) lack of technology and analytical methodology to produce oils conforming to international standards and market requirements, and (ii) inaccessibility and lack of commercial information systems and contacts to the protected international markets. Local use of these oils is restricted due to the lack of know-how for downstream processing of the oils to produce aroma chemicals and fragrance substances. Development of the industrial utilization of aromatic plants will be economically very important and useful to the developing countries both in terms of export earnings and import substitution of fragrance substances.

(c) Establishment of standards and methods of quality, safety and efficacy assessment ^{4/}

58. Production on industrial scale and pilot plant technology must be supplemented and supported by modern analytical instrumentation for quality assessment. It has to be borne in mind that rigorous quality control requirements precede acceptance of raw materials, plant extracts, isolates, and pure phytochemicals, as well as finished products, in international trade. Thus, systematic record inventories should be maintained and modern instrumental analytical methods should be used for quality assessment and standardization of plant-derived products and for quality control of industrial scale-manufactured pharmaceuticals.

59. Safety and efficacy assessment should cover all relevant aspects. Side-effects should be documented according to pharmacovigilance principles and these should be part of the literature.

(d) Product development and stability studies

60. Attempts should be made to develop the traditional medicinal preparations into products of high quality, efficacy and stability. The stability studies have to be conducted to determine proper expiration dates to suit the climatic and storage conditions in the countries.

61. A programme would remain incomplete unless and until there can be developed standardized products which are suitable for indigenous health care programmes and products with quality assurance acceptable in international trade which could generate foreign exchange. There should be a defined formula including excipient, procedure for manufacture, and specification for each product. The physical and chemical stability of the product in the final marketing pack thus should be tested under defined storage conditions and shelf-life should be established.

(e) Conducting pharmacological screening, toxicity tests, preclinical and clinical studies

62. Pharmacological and clinical studies are the leading discipline of the programme. It has to be noted that finished formulated preparations will find little prospects of being accepted locally or in the industrialized countries as they would face formidable regulatory barriers with demanding requirements of clinical, preclinical and analytical data. Thus conducting of controlled pharmacological, toxicity and clinical studies and tests etc. would need to be introduced as a matter of routine. The competent authority for assistance in this area is, for instance, WHO.

(f) Regulatory requirements

63. The significance of fulfilling regulatory requirements is of paramount importance. The regulatory requirements for admission of products into local therapeutic usage is largely a matter for the ministries of health. Analytical profiles and toxicological parameters will have to be determined prior to acceptance of standardized and reproducible preparations. The registration and regulatory authorities should evolve guidelines on herbal assessment and safety, taking into consideration the work done by WHO and other international bodies.

^{4/} Report of the Consultation to Review the Draft Guidelines for the Assessment of Herbal Medicine, WHO/TRM/91.3.

64. The registration of herbal preparations for use in modern therapy or health care systems has been difficult due to the regulatory requirements of efficacy, toxicity and quality control. However, some countries have initiated steps for registration for sale of selected preparations through herbal and food stores.

(g) Identification of training requirements

65. Educated manpower capable of absorbing specialized technical and management skills would be needed. The support of academic, vocational and training institutions could play an important role in providing manpower with adequate technical and management background in specialized skills and experience. The curricula of the concerned departments in the institutes, universities etc. should be designed to develop manpower needed for the phytopharmaceutical industry and international support in building up the requisite expertise may be sought.

66. Pragmatic approaches to agro- and industrial technological development aspects may include the following:

- (a) Upgrading of cultivation techniques and introduction of good agricultural practices;
- (b) Steps towards conservation of plants, establishment of germ plasma banks, etc.;
- (c) Steps towards facilitating the development and transfer of technology and modernization of processes for the production of herbal preparations, phytopharmaceuticals, phytochemicals, aroma chemicals and essential oils, giving due recognition to the importance of good manufacturing practices (GMP);
- (d) Harmonization of activities of academic and technological institutes to facilitate development and absorption of technologies and cost-cutting methodologies;
- (e) Establishment of manufacturers associations and strengthening of linkages between manufacturers and trade associations;
- (f) Establishment of standards and methods for quality assurance, pharmacological evaluation and work on regulatory aspects.

C. Need for strengthening research and development activities

67. The convergence of economic, health and environmental concerns has created a powerful set of factors towards revaluing the usefulness of medicinal and aromatic plants. The programme of drug development demands multidisciplinary capabilities. The list of plant-derived drugs indicates clearly that as a result of the scientific follow-up of well-known plants used in traditional medicine, a fair percentage of useful drugs have entered modern

therapy. The same is true of the recent Chinese experience. To quote from a WHO publication: "There is therefore much in favour of establishing programmes for producing standardized and safe galenical traditional preparations for potential use in primary health care, with the eventual aim of discovering their active principles. . . Even if the active principles have not yet been identified in some of the plants used in traditional medicine, historical evidence of the value of such plants could result in useful preparations provided they are safe. Evaluation of safety therefore should be a prime consideration even at the expense of establishing efficacy of the preparation."^{1/}

68. Thus very briefly the salient R&D requirements would include:

- Ensurement of quality and consistency in plant raw materials;
- Validating claims of traditional therapies using modern methodology;
- Development of standards of quality assessment and ensurement for starting materials and finished products;
- Development of modern process technology for production of medicinal products, its assimilation and improvement to make the product competitive;
- Development of new formulations and dosage forms suited to climatic conditions;
- Determining the role of traditional system-based remedies in current health care delivery systems;
- Investigations leading to the development of new drugs, particularly where current remedies are unavailable or unsatisfactory and search for new plant sources;
- Bioequivalence, bioavailability and pharmacokinetic studies on the dosage forms developed;
- Development and introduction of cost-cutting methodologies, including in-vitro screening through better techniques.

69. Research and development objectives and goals must therefore be determined with the above considerations in view.

C.1 R&D is an essential ingredient with whose backing national industry can grow properly. A research base is the insurance against future backwardness and underdevelopment. It is therefore necessary to take policy measures, formulate a plan of action and develop an institutional framework so as to establish the R&D facilities on sound footings.

C.2 The pace of technological change is so quick that no industry can hope to keep in house all the scientists they would need to do basic and strategic research. Industry thus needs co-operation with technological institutions and academia to keep it up-to-date at a time of rapid technological change. The importance of strong links between industry, academia and technological institutions is stressed.

To facilitate development of new drugs, consideration could be given to assembling a research team of independently minded scientists and academics all with a different type of training and attitude towards commercially oriented research.

^{1/} Medicinal Plants in Therapy - Bulletin of the World Health Organization, 63(6).

- C.3 In the field of phytopharmaceuticals the disciplines which need special attention for research activities include: agronomical, post-harvest, process technology (pilot and laboratory scale), development of phyto-formulations, quality and stability, biological activity studies, toxicity studies, chemical testing and marketing of products.
- C.4 Traditional drugs offer much scope for improvement. Research on these drugs need to be aimed at (i) development of new drugs, and (ii) enhancement of their acceptability and usefulness through application of modern production and quality control techniques.
- C.5 In the context of R&D, the development, storage and mechanism for exchange of information and data is of importance. Availability of accurate and updated information is a key to success and enhances co-operation between countries and regions. A common plan for the information network can be drawn and duplication of research and development activities in the region can be avoided.
- C.6 R&D institutions play a significant role. There should be established objectives for such institutions. Schemes of regional and international co-operation should strengthen R&D activities and institutions. There should be a mechanism for accruing benefits from centralized R&D activities.
- C.7 Consideration should be given to commercialization of research and development results. Common problems and factors affecting the commercialization process should be studied and plans and guidelines should be worked out for smooth operations. Mechanisms for commercialization should be established.
70. A practical approach to encourage and develop research and development facilities may include:

- (a) Development of a comprehensive plan for R&D activities with defined goals and objectives, including development of new drugs, new formulations from traditional pharmacopoeias, phytochemicals, improvement of process technologies, analytical techniques for agro- and industrial aspects, and pharmacological research on traditional medicine;
- (b) Development of a code of practice for interaction between academic, research institutions and industry and harmonization of their activities;
- (c) Strengthening the research centres, development of mechanisms for exchange of information, data, expertise and manpower, etc.
- (d) Initiation of steps for safeguarding the interests of research institutes through development of guidelines related to intellectual property rights; taking up steps towards commercialization of R&D results;
- (e) Development of joint research programmes.

D. Human resource development for specialized technical and managerial skills; Entrepreneurship and marketing aspects

71. The importance of availability of trained personnel for establishing and operating industrial units is recognized. Well educated and well trained manpower capable of absorbing special technical and management skills is an asset. There should be an appropriate infrastructure for training of manpower. Academic vocational and technical training institutions could play an important role in providing adequate technical and management background on which to base required skills and experience. The approach to human resource development has to be comprehensive and multifaceted so as to cover both the physical and the institutional infrastructure required for industrial development. The curricula of universities should be designed to equip manpower with the necessary background for absorbing and developing the needed skills.

72. Each country should draw up its needs for training covering the higher management level as well as the technician level. The training components could cover exchange of experience in operation of industry, process technology, quality control, maintenance of equipment and machinery etc., as well as marketing of products and business management. The manufacturing enterprises need to encourage development of apprenticeship schemes and other forms of in-plant training and Governments should encourage such schemes through provision of incentives.

73. UNIDO's training programme strategy includes invariably:

- Training organized in co-operation with the government of a specific country;
- Training in the form of workshops, seminars, group programmes, in collaboration with government or industry, covering specific fields. These programmes are more intensive and comprise theoretical and practical aspects;
- Training as an element of technical assistance projects.

74. Possibilities of co-operation between developed and developing countries and among developing countries themselves for imparting training in all principal areas related to infrastructural and specific technical and management fields should be explored and encouraged.

75. The medicinal and aromatic plant-based industry provides routes of entry for domestic entrepreneurship in setting up small-scale industrial units. Policy and support measures for potential investors, availability of information on markets, technology, sources of finance, ready access to credits, etc. are some of the areas that need attention.

76. The market conditions for plants and plant-based products are changing rapidly. With the growing demand also the specifications and regulatory requirements are tightening up. To ensure continuity of supply of quality material, steps are being taken by interested parties. Trade is presently not well organized. Commerce authorities should help to regularize matters. There is need for establishing an information system relating to trade and marketing aspects of medicinal and aromatic plant-based raw materials and products.

77. The practical approaches for development of human resources, as well as entrepreneurship and trade aspects, may include the following:

- (a) Education and training is an important component of human resource development. Academic, vocational and technical training institutions play a significant role. The agro-, industrial and medical fields need special attention for manpower development;
- (b) Introduction of the subject of botany and medicinal plant-based medicaments into the curricula of schools of health professionals and related disciplines;
- (c) Training needs should be determined both for higher management, technicians and medical professionals; exchange of experience in development of industrial infrastructure, in operation of industry, process technology, quality control, maintenance of machinery, marketing of products, business management could be major areas of thrust;
- (d) Training in the form of workshops, seminars, etc., as well as development of apprenticeship schemes and in-plant training by enterprises, needs to be encouraged;
- (e) To encourage entrepreneurship, attention needs to be given to creating industrial support schemes, information on technology, sources of finances, incentives and credit facilities, etc., as well as development of information systems on commercial aspects and development of schemes to increase value added for phyto raw and processed materials.

E. Regional and international co-operation for the development of the subsector

78. The development of the subsector in a country requires simultaneous action on many fronts. Such action has to originate from efforts at the national level. The resources available in many of the developing countries, however, are not sufficient for the purpose. Moreover, many developing countries have limited natural resources or they are too small to achieve the economy of scale that is critical to the operation of certain parts of the supply, production and information system, etc.

79. Development of new drugs using leads from traditional medicine is a very expensive process unaffordable to many developing countries. This activity has to be done in collaboration with industrialized countries or companies with proper safeguards to protect the rights of the institute or country supplying the information. The activities may be carried out through regional co-operation by a group of countries.

80. Co-operation is to be based upon clearly defined objectives of mutual benefit to the parties and will involve different forms of administrative and legal arrangements to determine the role, obligations and responsibilities of the parties to obtain the desired objectives. Special steering committees at regional levels could be established with the objective of enhancing co-operation.

Co-operation extended at subregional, regional and international levels, for instance enterprise-to-enterprise co-operation or co-operation between enterprises and R&D centres in different countries, have proved to be most useful in improving operational and production economics of industrial/research organizations. The co-operative action could cover broadly many areas from joint purchases, production, development of technology, to research and development efforts and trade, etc, as well as exchange of information and experiences in basic and applied areas, studies etc. on specific disease patterns and particular conditions of developing countries.

81. With the assistance of international organizations, such as WHO, UNIDO, FAO, ITC, etc. and regional steering committees for co-operation more specific co-operative efforts for the development of the subsector in agronomical, process technology, regulatory, quality control, human resource development and trade aspects, etc. can be directed, covering aspects such as:

- (a) Establishment of R&D centres and enhancing their co-operation with academic and technological institutes with a view to facilitating the absorption and improvement of imported technologies to suit local conditions, as well as conducting joint research programmes on plants used specifically for ailments that are prevalent in a given region or for ailments for which no adequate remedy exists;
- (b) Identification and development of known therapeutically active plant-derived substances as a means to augment national essential drug requirements;
- (c) Plans for co-operation related to enforcement of steps for protection and conservation of medicinal plant resources;
- (d) Development of a programme for improvement of traditional medicine; strategies for facilitating rationalization of production on an industrial scale to meet the primary health care needs; development of agro- and process technologies and sharing the innovations among countries of the region, as well as joint production of phytopharmaceutical preparations, development of a joint quality protocol, safety standards, standardization of bioassay procedures and implementation of regulatory requirements;
- (e) Plans for joint development, production and usage of essential oils, aroma chemicals and fragrance substances;
- (f) Collation and exchange of information, establishment of regional data bases on plants as well as monitoring of development of herbal medicine;
- (g) Co-operation in development of guidelines for secrecy agreements, licensing procedures, patents and intellectual property rights etc. for plant-based medicine and to encourage interaction between research institutions and industry;
- (h) Co-operation in purchase of equipment/machinery and negotiation of contracts for technologies;
- (i) Organizing workshops for training as well as exchange of ideas and experiences at technical and management levels;
- (j) Development of entrepreneurship and management and marketing initiatives, including market intelligence and information system, and strategies to facilitate rationalization of exports and trade etc.;^{2/}

^{2/} Better Utilization of Medicinal Plants. The Phytopharmaceutical Supply System in China; PPD.47.

(k) Plans for co-operation for investments in joint ventures, etc.

82. From time to time regional schemes of co-operation surface amongst regional groupings, i.e. ASEAN (Association of South-East Asian Nations), Andean Group, CEAO (Communauté économique de l'Afrique de l'Ouest), Commonwealth Regional Secretariat for East and Central Africa, Copptec, etc. It has been observed that amongst the industrial sectors for development, the pharmaceutical sector figures out in the schemes.^{6/} The subsector related to medicinal and aromatic plants can also be included prominently under pharmaceuticals and a methodology should be developed for bringing the work carried out by such groups nearer so as to maximize on the benefits to be accrued from such co-operative schemes.

83. The pragmatic approach for achieving regional and international co-operation for the development of the subsector may include:

- (a) Establishment of regional steering committees to formulate the direction of mutual co-operation;
- (b) Development of joint programmes on aspects such as agro- and processing technologies, research and development, training of manpower, trade and other areas, as well as setting-up of regional centres for the development and harmonization of the programmes;
- (c) Setting-up of regional information and data centres; exchange of modern and classic medical literature;
- (d) Establishment of regional programmes for exchange of experiences and personnel, including exchange through international agencies;
- (e) Co-ordination and harmonization of regulatory measures;
- (f) Establishment and strengthening of manufacturers and trade associations and establishment of an information system to exchange technical information as well as to enhance trade and marketing of phyto raw and processed materials;
- (g) Strengthening of capabilities through the establishment of regional research and development centres;
- (h) Establishment of regional engineering design and service centres to encourage the setting-up of industrial production units and local fabrication of pilot plants and other equipment, etc.;
- (i) Co-operation in development of entrepreneurship, joint ventures, etc.
- (j) Organizing periodic symposia as well as meetings of the competent international agencies, federations and associations active in the area of the medicinal and aromatic plant subsector.

^{6/} Factors Having a Bearing on Industrial Drug Policies; ID/WG.466/6(SPEC.).

PART III: CONCLUSIONS AND CONSIDERATIONS ON SOME MEASURES FOR THE DEVELOPMENT OF THE SUBSECTOR

84. In conclusion, while strategy and policy formulations for an integrated development are by their very nature country specific, there are common concerns and preoccupations in the developing countries which need to be addressed to promote the integrated sustained development of plant-based industry. From the considerations discussed in the foregoing sections and practical approaches as referred to comprehensively on pages 10, 15, 17, 19, and 21, respectively, as well as the points highlighted by the expert group meetings convened by UNIDO on the subject, besides those details and among others, some areas of thrusts commended for attention and further elaboration by the Consultation, include the following:

(i) Development and adoption of strategies, policies and methodologies for an integrated approach towards the development of phytochemical, phytopharmaceutical and herbal preparation industries;

(ii) Initiation of steps towards the establishment of national policy and planning committees to draw up policies and strategies for overall domestic development of the subsector covering aspects as contained in para. 24, and guidelines on aspects such as introduction of the subject of medicinal plant-based medicaments in the curricula of schools of health professionals, promotion of the use of herbal medicine in national health delivery systems, establishment of regulatory authorities, steps towards improvement of agricultural and industrial production aspects;

(iii) Conducting systematic surveys and exploration of natural resources to have assured supply of raw materials for the phyto-based industry and thus stimulate investment in industrial production facilities;

(iv) Establishment of mechanisms for regional co-operation for preservation, propagation, crop improvement, etc. of medicinal and aromatic plants, in co-operation with international organizations;

(v) Initiatives leading to the development of indigenous skills and capabilities to adopt and innovate technologies for agro-, industrial production and processing of plant materials for the production of medicaments as well as aroma chemicals and essential oils, etc.; Intensification of efforts to promote the setting-up of pilot processing plants;

(vi) Initiatives for international co-operation for the development of methodologies for the assessment of therapeutic value of medicinal plants, their processing as raw materials and as pharmaceutical and herbal preparations, the regulatory needs for introducing plant-derived pharmaceuticals and herbal preparations from traditional pharmacopoeias into health-care delivery systems;

(vii) Establishment at subregional, regional and international levels of information networks, covering technical and other aspects, and inter-institutional links for the development of the phytopharmaceutical and essential oil industries;

(viii) Co-operation in the establishment and strengthening of research and development capabilities in developing countries, harmonization of the research programme and enhancement of their co-operation with academic and technological institutes with the objective of facilitating the absorption and improvement of imported technologies to suit local conditions, and development of joint R&D activities and introduction of cost-reducing methodologies at regional and international levels;

(ix) Establishment of engineering design and services centres to facilitate the setting-up of production units and to encourage local fabrication of pilot plants and other equipment through co-operation with international organizations by provision of technical and financial inputs;

(x) Co-operation in the development of human resources capable of absorbing specialized technical and management skills; international organizations to assist in development of programmes and securing finances for the same;

(xi) Co-operation in the development of entrepreneurship, trade, measures to increase value added for products, overall marketing of raw and processed products and setting-up of commercial information networks, etc.;

(xii) Co-operation in relation to the financing of selected research and development activities and joint venture projects.